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Cox et al.

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(54) **APPARATUS FOR USE WITH NEEDLE INSERTION GUIDANCE SYSTEM**

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See application file for complete search history.

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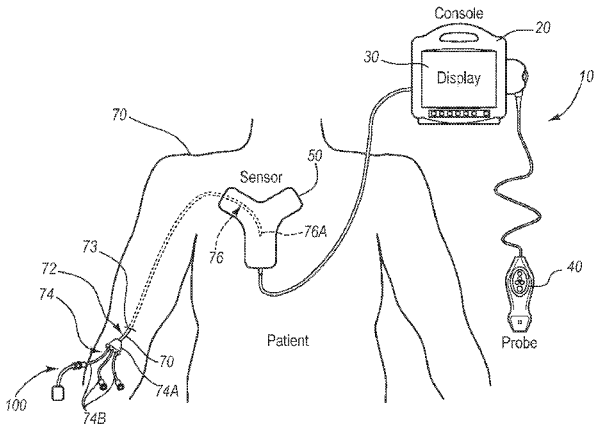
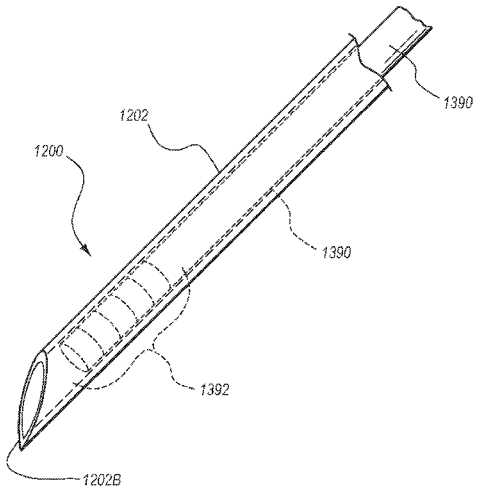
(57) **ABSTRACT**

A guidance system for assisting with the insertion of a needle into a patient body is disclosed. The guidance system utilizes ultrasound imaging or other suitable imaging technology. In one embodiment, the guidance system comprises an imaging device including a probe for producing an image of an internal body portion target, such as a vessel. One or more sensors are included with the probe. The sensors sense a detectable characteristic related to the needle, such as a magnetic field of a magnet included with the needle. The system includes a processor that uses data relating to the sensed characteristic to determine a 3-D position of the needle. The system includes a display for depicting the position of the needle. The needle can include a donut-shaped magnet disposed about the needle cannula, or a removable stylet with a magnetic element and a strain gauge for detection of the needle distal tip.

5 Claims, 32 Drawing Sheets





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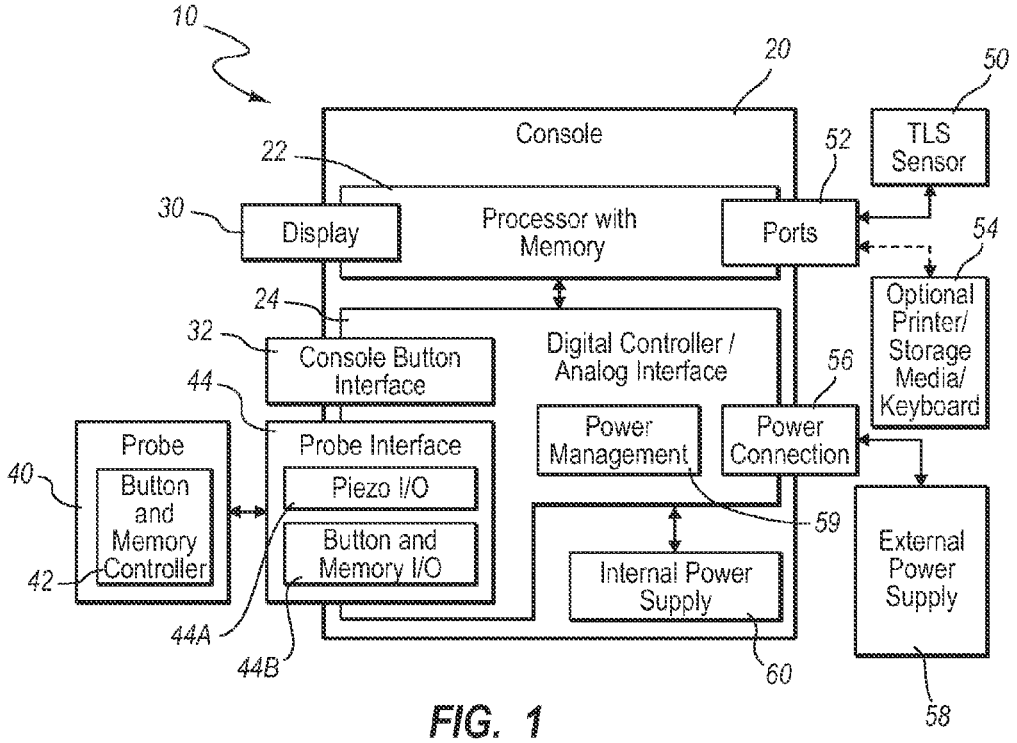
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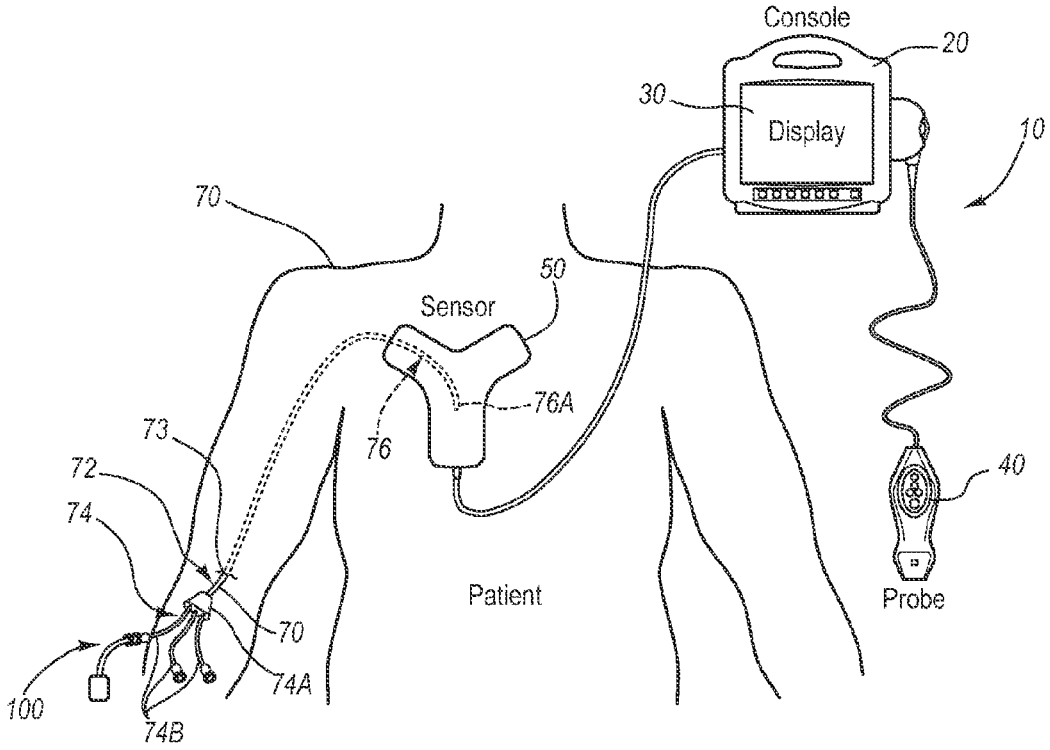
50
Console
22
52
TLS Sensor
30
Display
Processor with Memory
Ports
54
24
Optional Printer/ Storage Media/ Keyboard
32
Console Button Interface
Digital Controller / Analog Interface
56
44
Probe Interface
Power Management
Power Connection
Probe
40
Button and Memory Controller
Piezo I/O
59
Button and Memory I/O
External Power Supply
42
Internal Power Supply
44A
44B
60
58

FIG. 1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Sensor
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70
Patient
Probe
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100
74B

FIG. 2

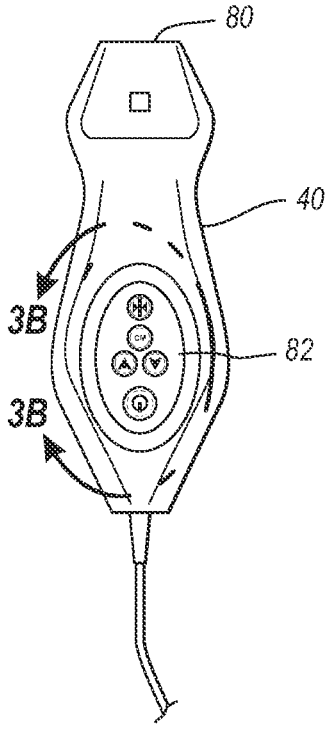


FIG. 3A

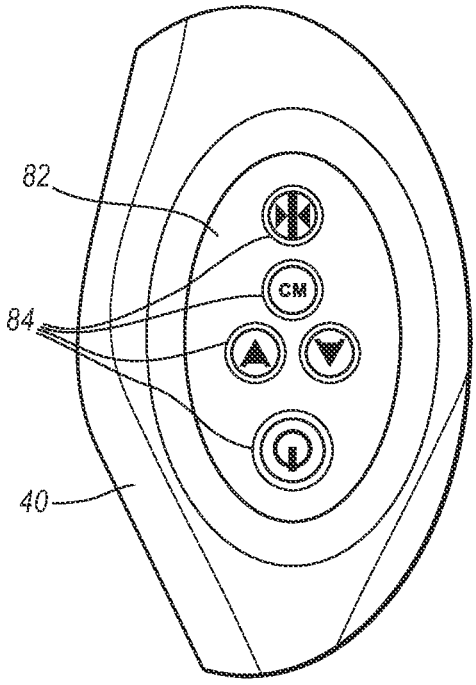
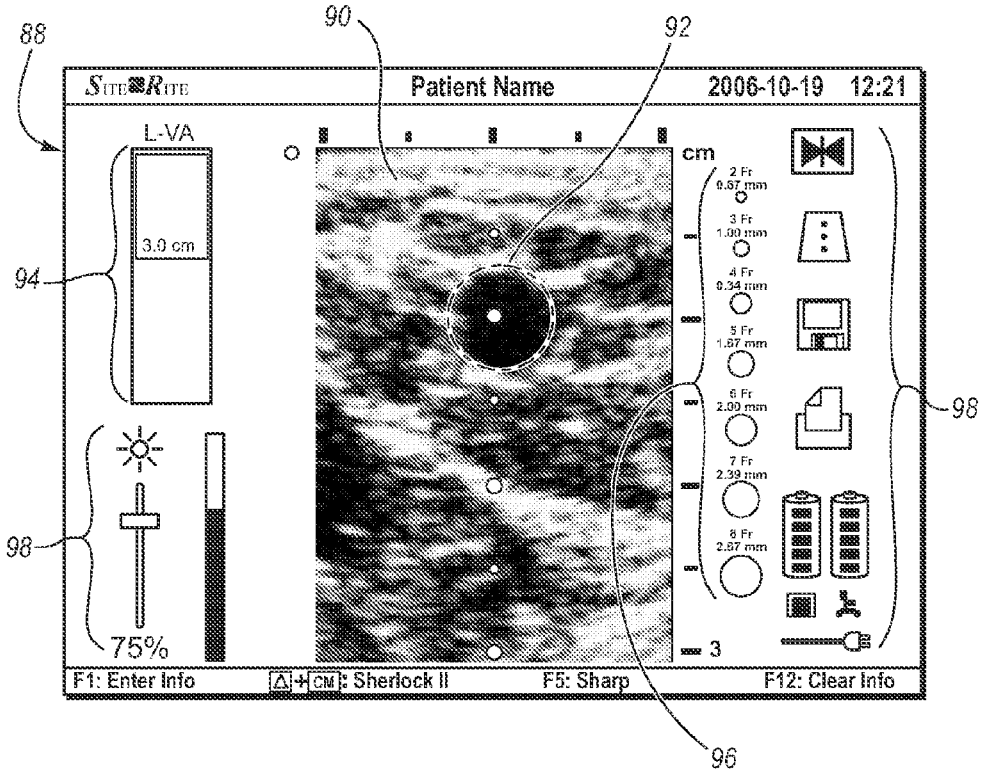


FIG. 3B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90
92
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Patient Name
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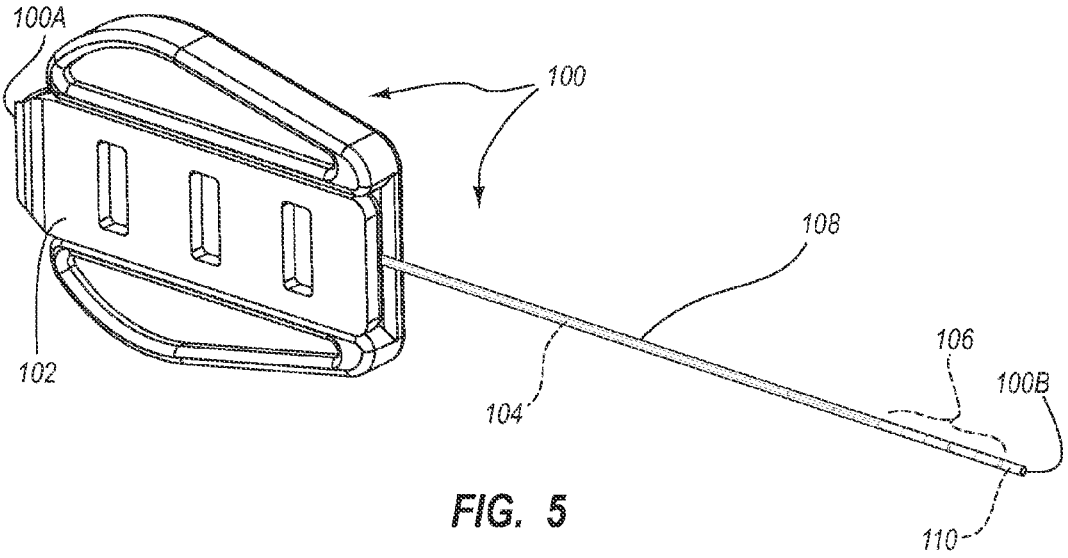
3.9 cm
94
cm
2 Fr 0.67 mm
3 Fr 1.00 mm
4 Fr 0.34 mm
5 Fr 1.67 mm
6 Fr 2.00 mm
7 Fr 2.39 mm
8 Fr 2.67 mm
98
98
75%
3
F1: Enter Info
Sherlock II
F5: Sharp
F12: Clear Info
96

FIG. 4


100A
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108
102
104
106
100B
110

FIG. 5

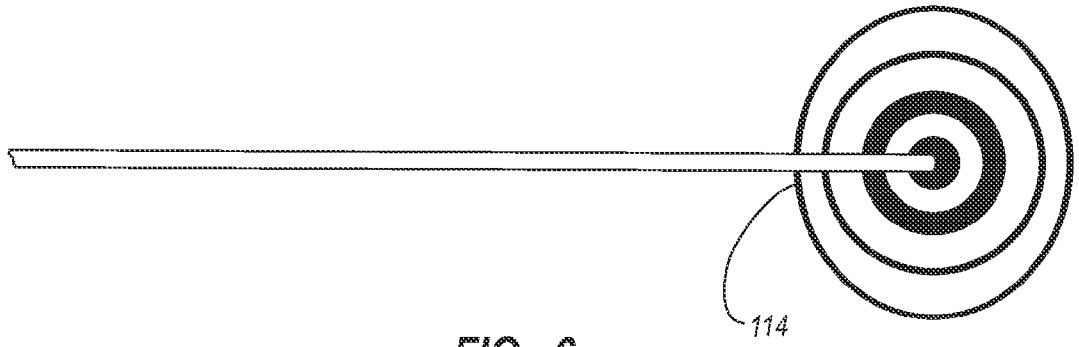

FIG. 6

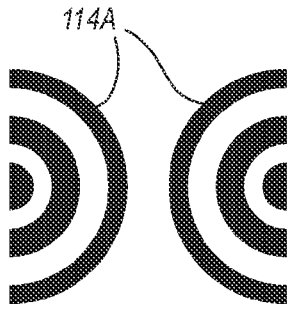

FIG. 7A

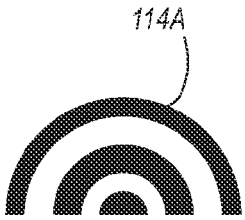

FIG. 7B

FIG. 7C

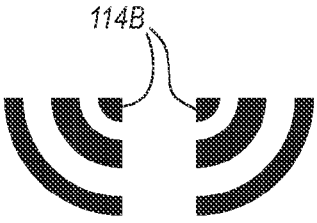

FIG. 7D

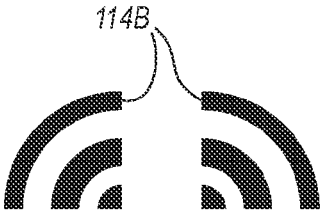

FIG. 7E

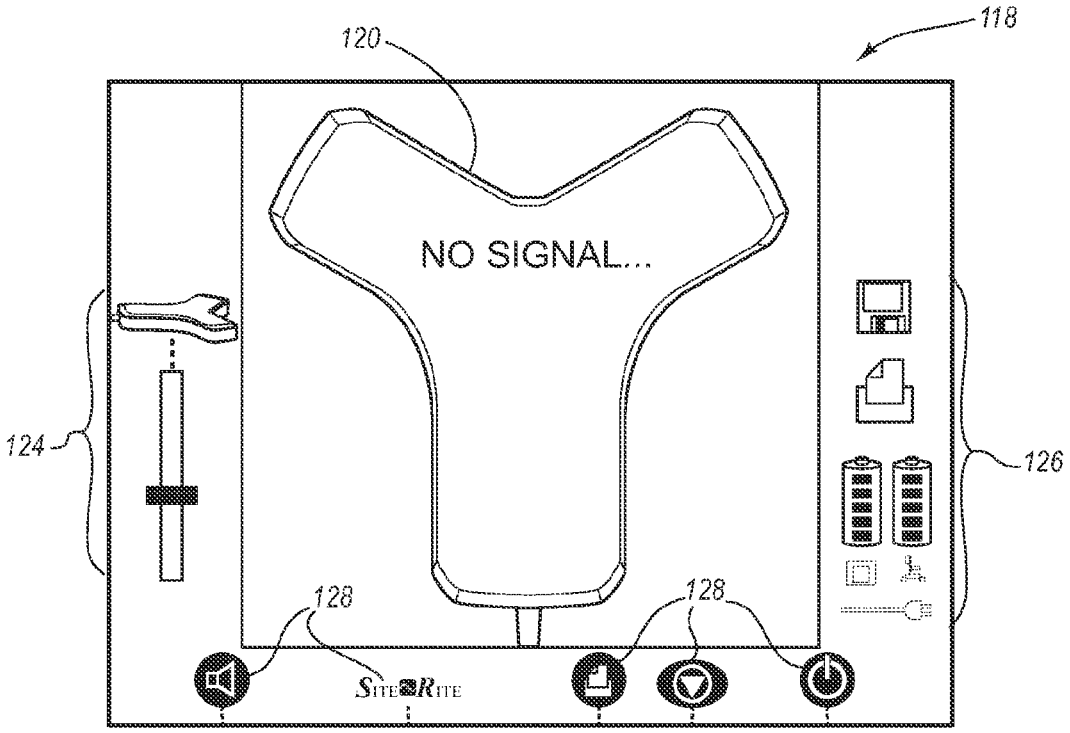
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FIG. 8A

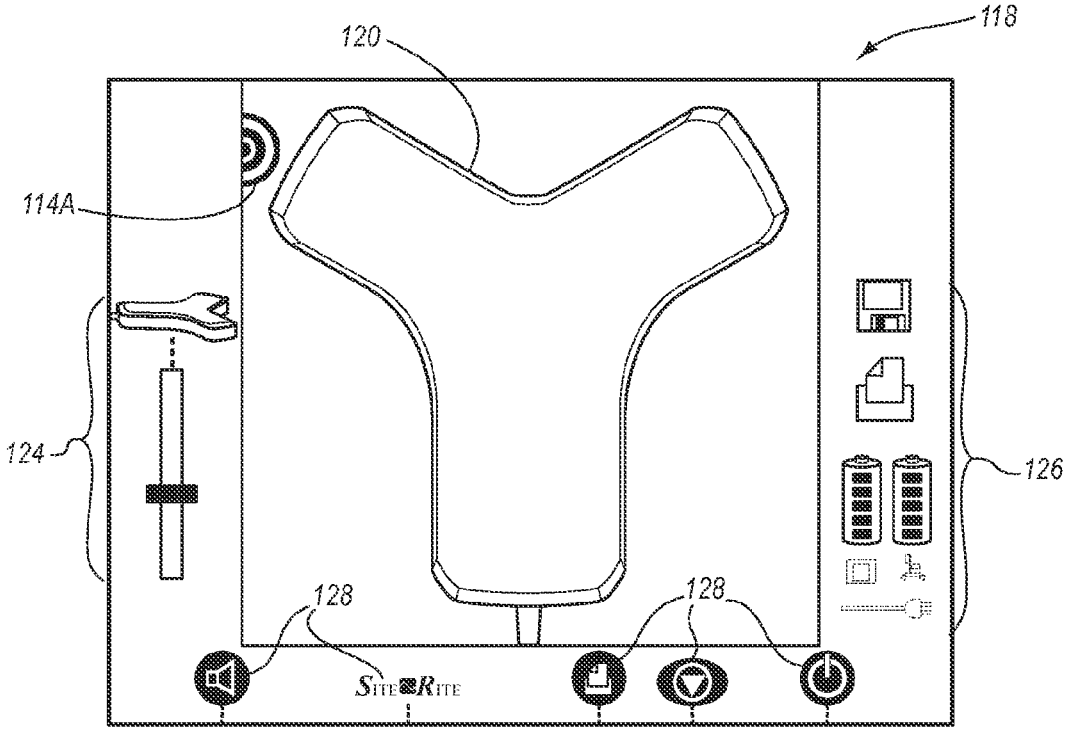
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FIG. 8B

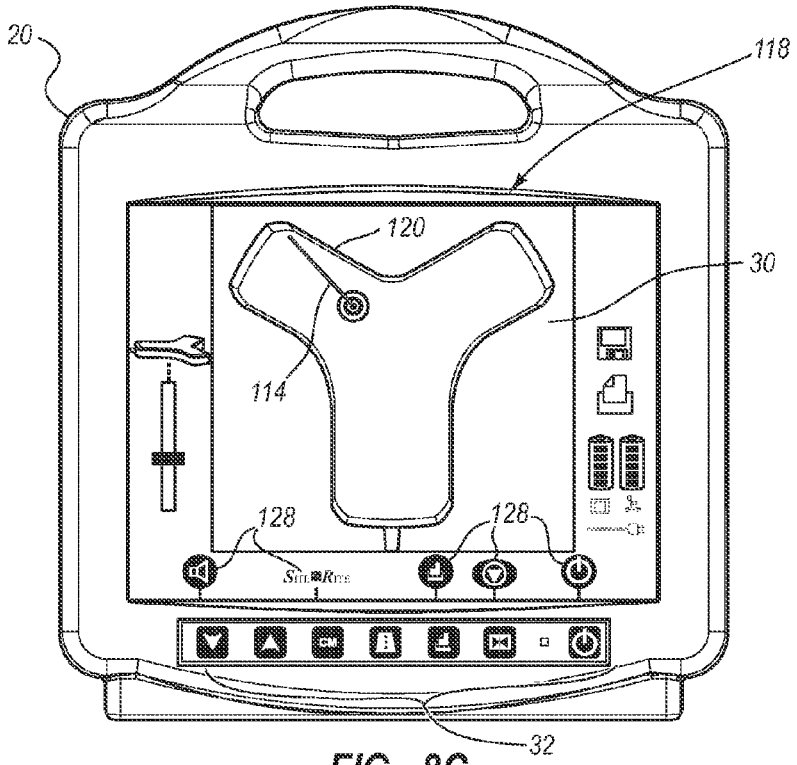
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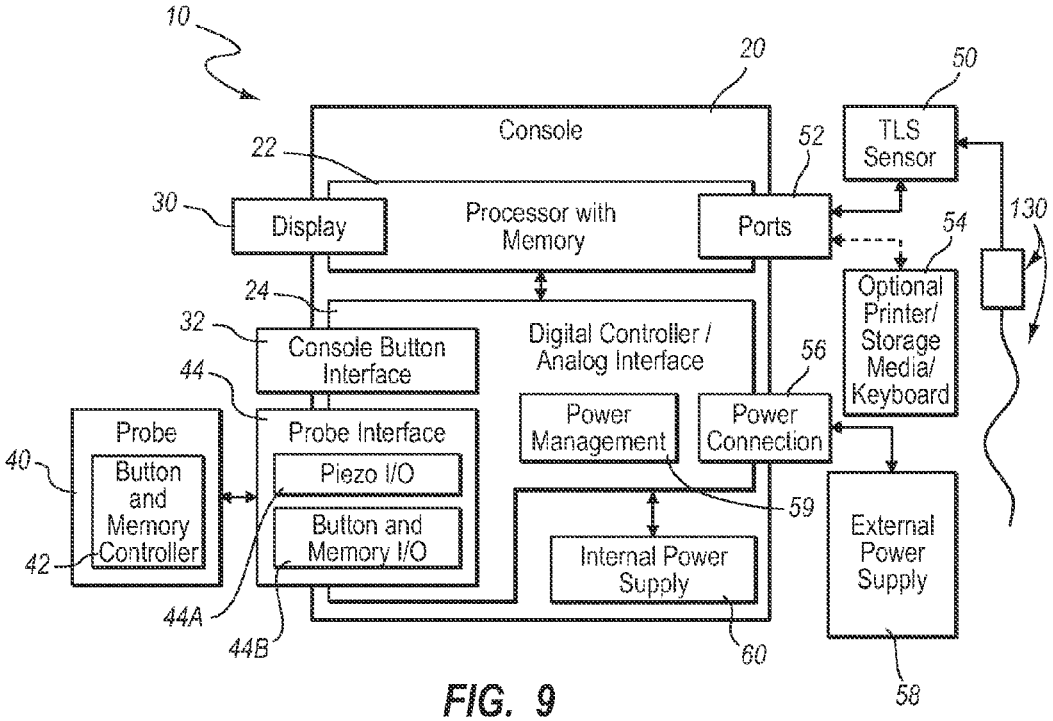
FIG. 8C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Console
TLS Sensor
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Display
Processor with Memory
Ports
54
130
24
Optional Printer/ Storage Media/ Keyboard
32
Console Button Interface
Digital Controller / Analog Interface
56
44
Probe Interface
Power Management
Power Connection
Probe
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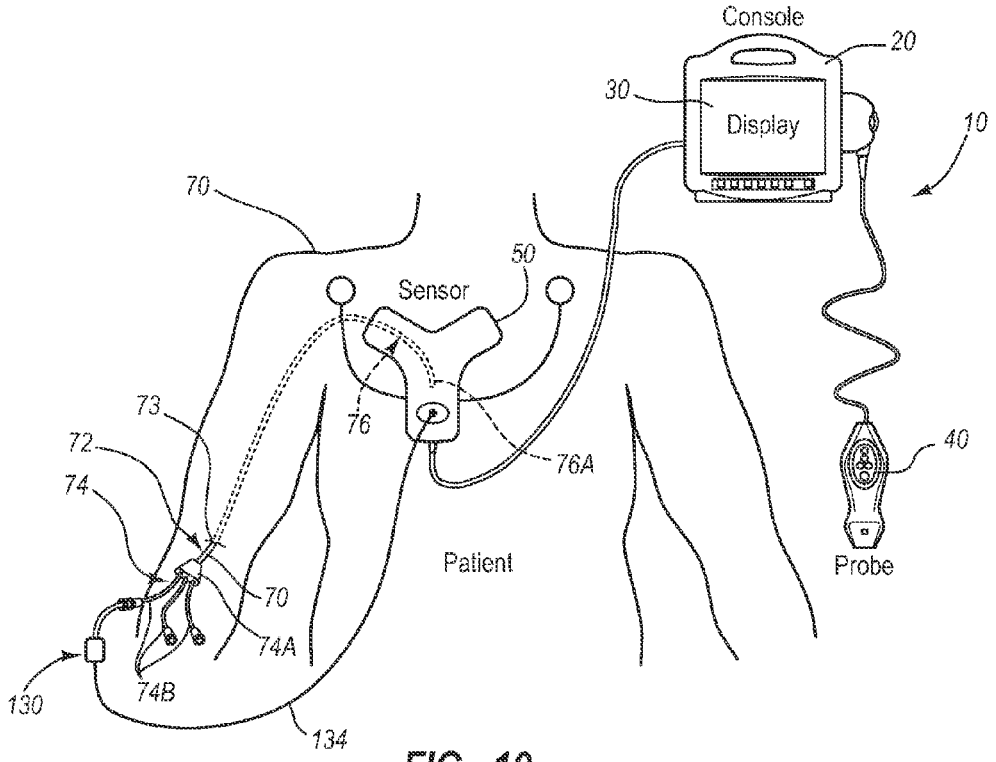
Button and Memory Controller
Piezo I/O
59
Button and Memory I/O
External Power Supply
42
Internal Power Supply
44A
44B
60
58

FIG. 9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Patient
Probe
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134

FIG. 10

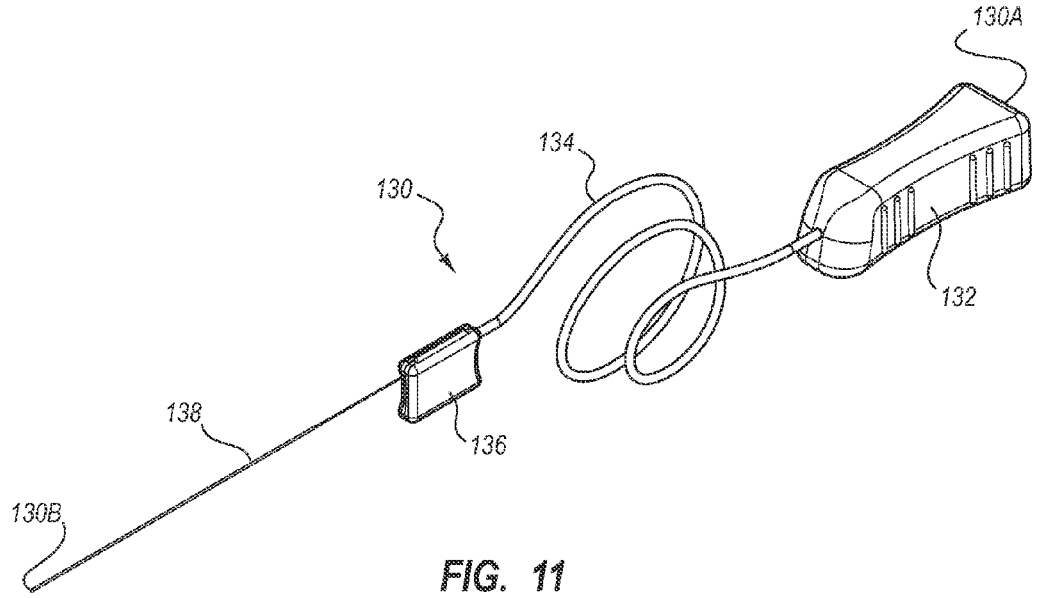
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FIG. 11

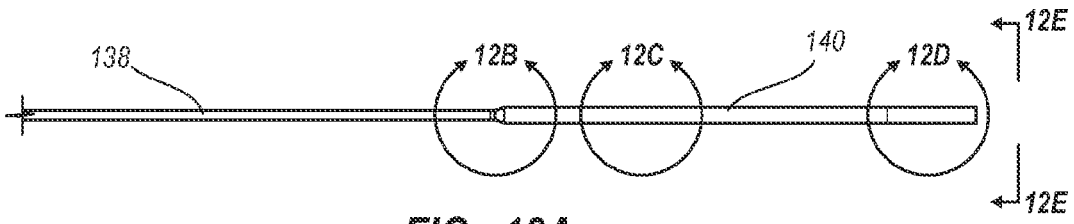

FIG. 12A

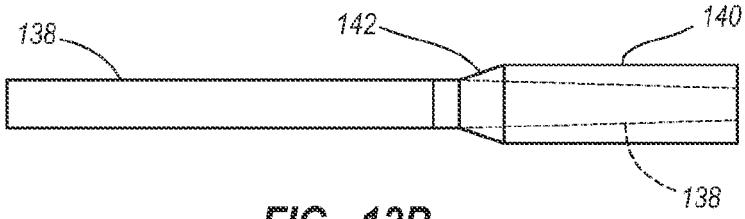

FIG. 12B

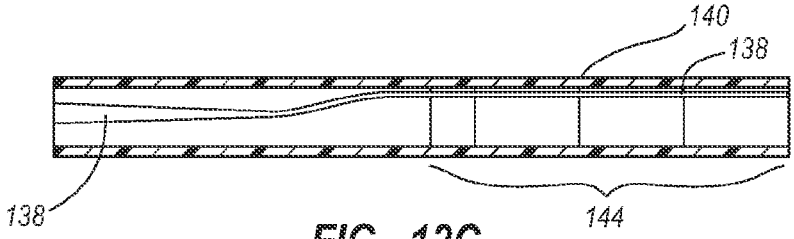

FIG. 12C

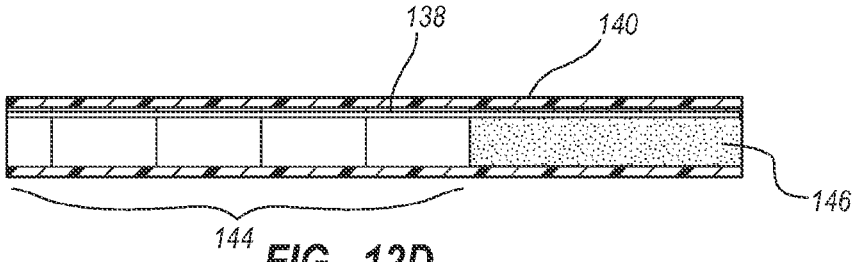

FIG. 12D

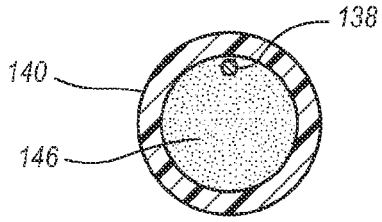

FIG. 12E

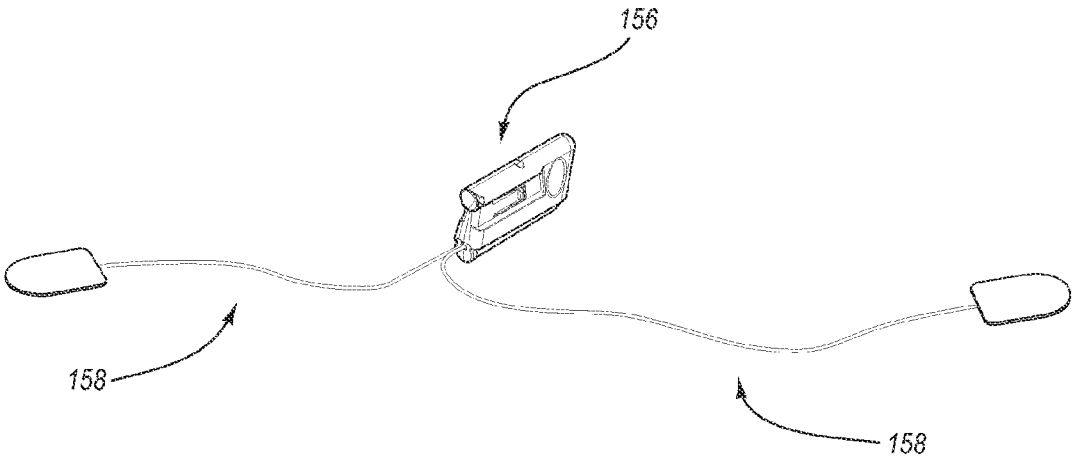

FIG. 13A

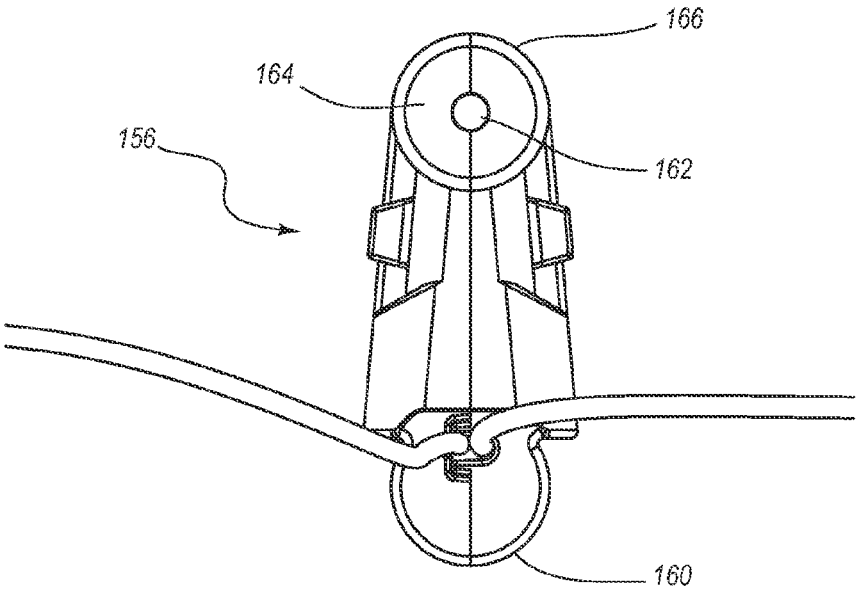

FIG. 13B

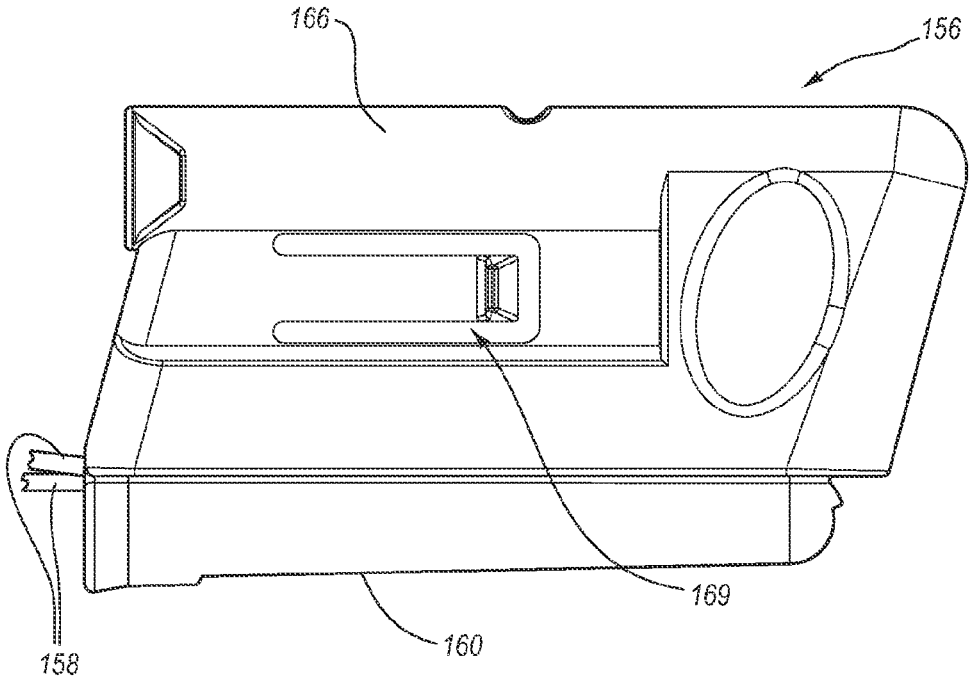

FIG. 13C

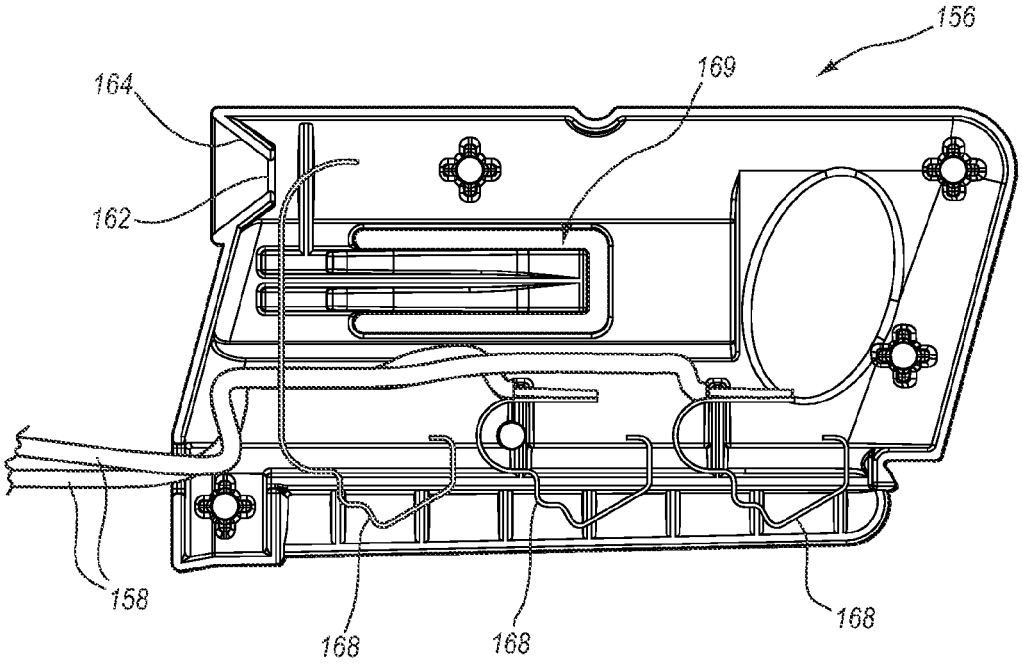

FIG. 13D

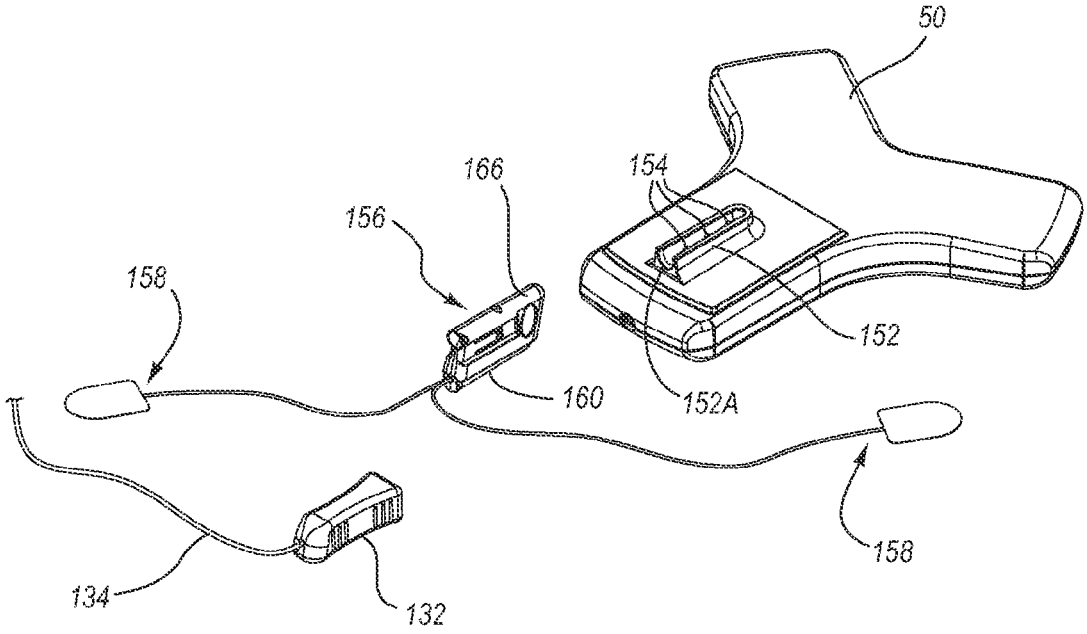

FIG. 14A

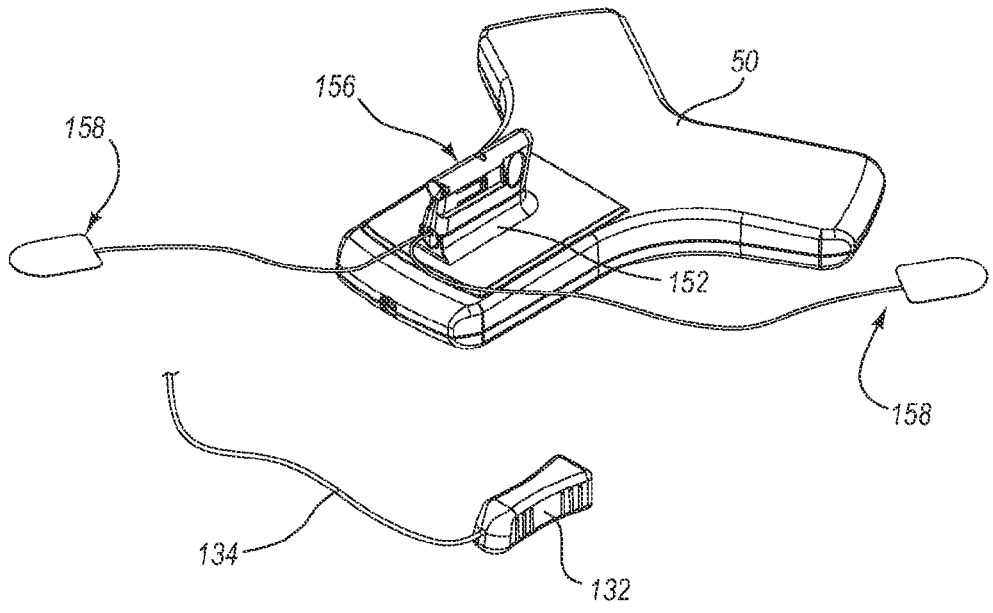

FIG. 14B

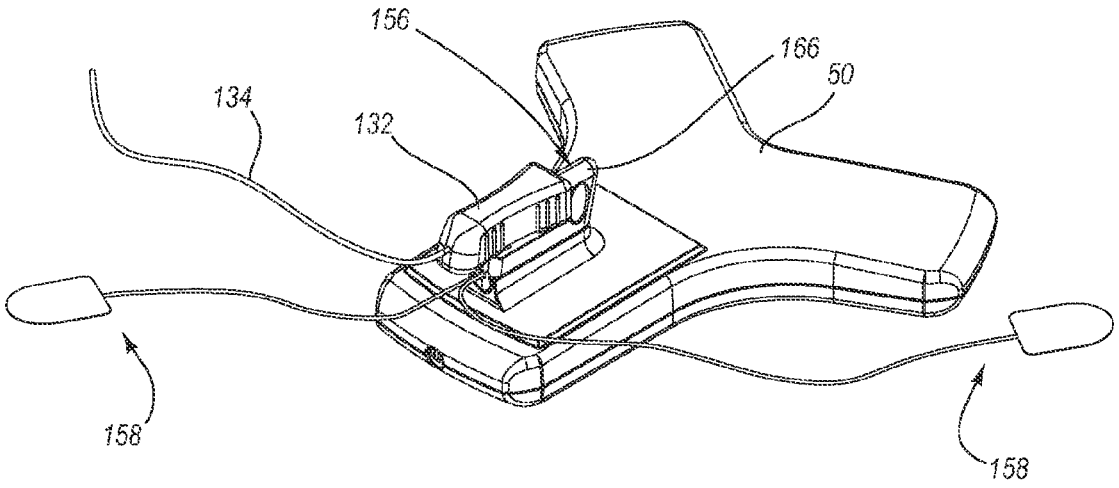

FIG. 14C

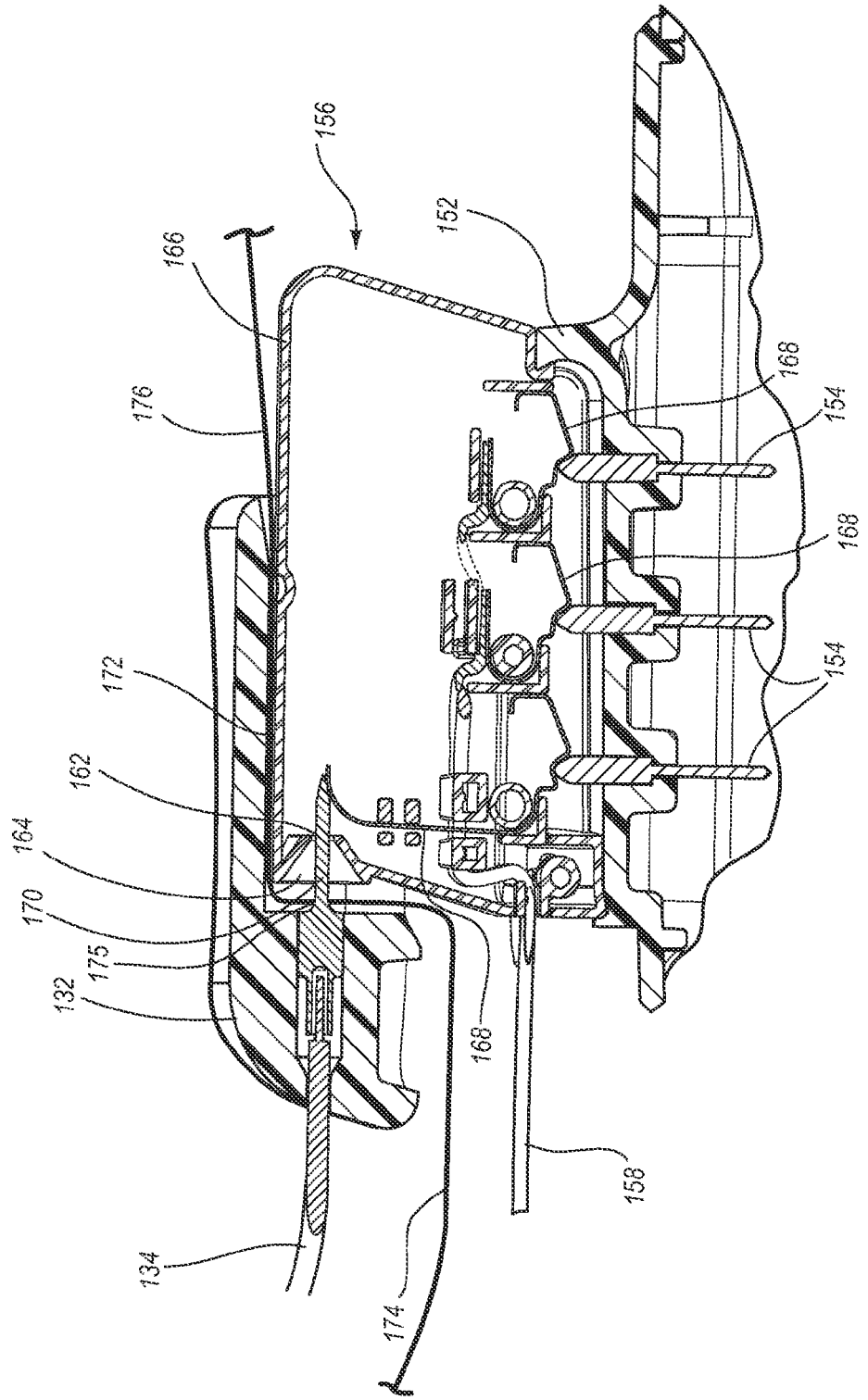
156
152
166
176
168
154
168
154
172
162
164
170
175
132
168
158
134
174

FIG. 15

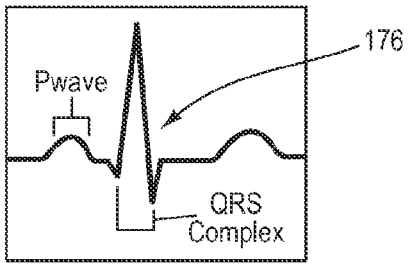
176
Pwave
QRS
Complex

FIG. 16

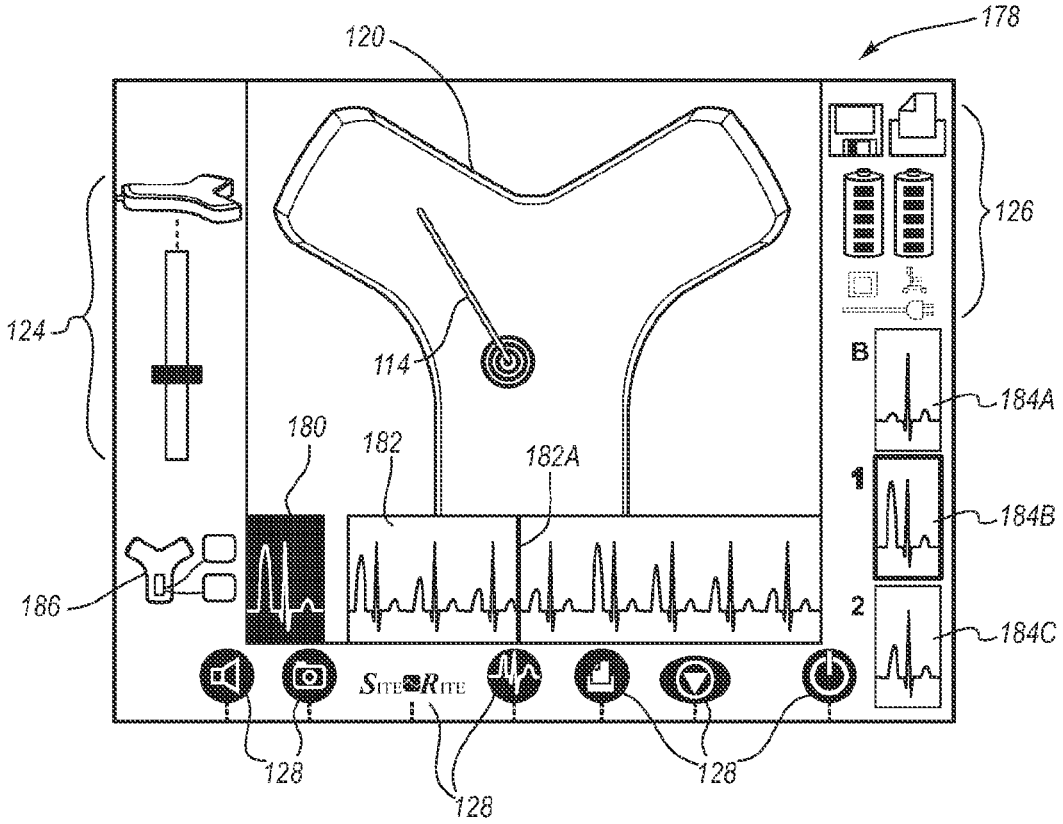
178
120
126
124
114
B
184A
180
182
182A
1
184B
186
2
184C
SITERITE
128
128
128

FIG. 17

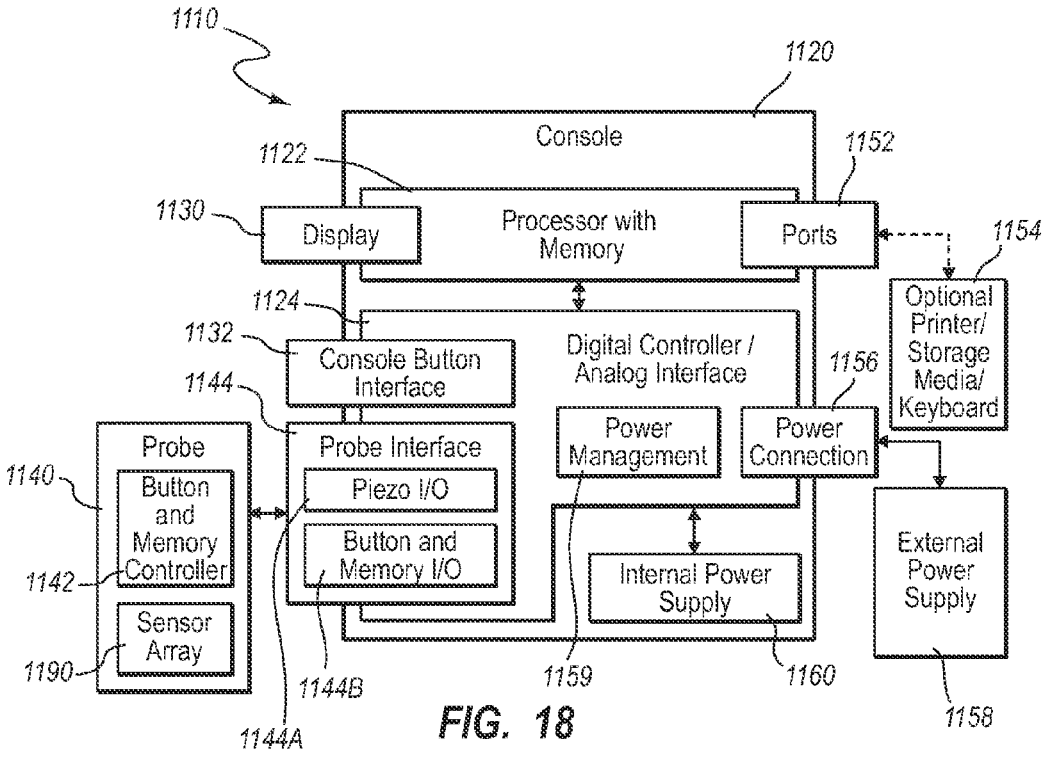
1110
1120
Console
1122
1152
1130
Display
Processor with Memory
Ports
1154
Optional Printer/ Storage Media/ Keyboard
1124
1132
Console Button Interface
Digital Controller / Analog Interface
1156
1144
Probe
Probe Interface
Power Management
Power Connection
1140
Button and Memory Controller
Piezo I/O
Button and Memory I/O
External Power Supply
1142
Sensor Array
Internal Power Supply
1190
1144B
1159
1160
1158
1144A

FIG. 18

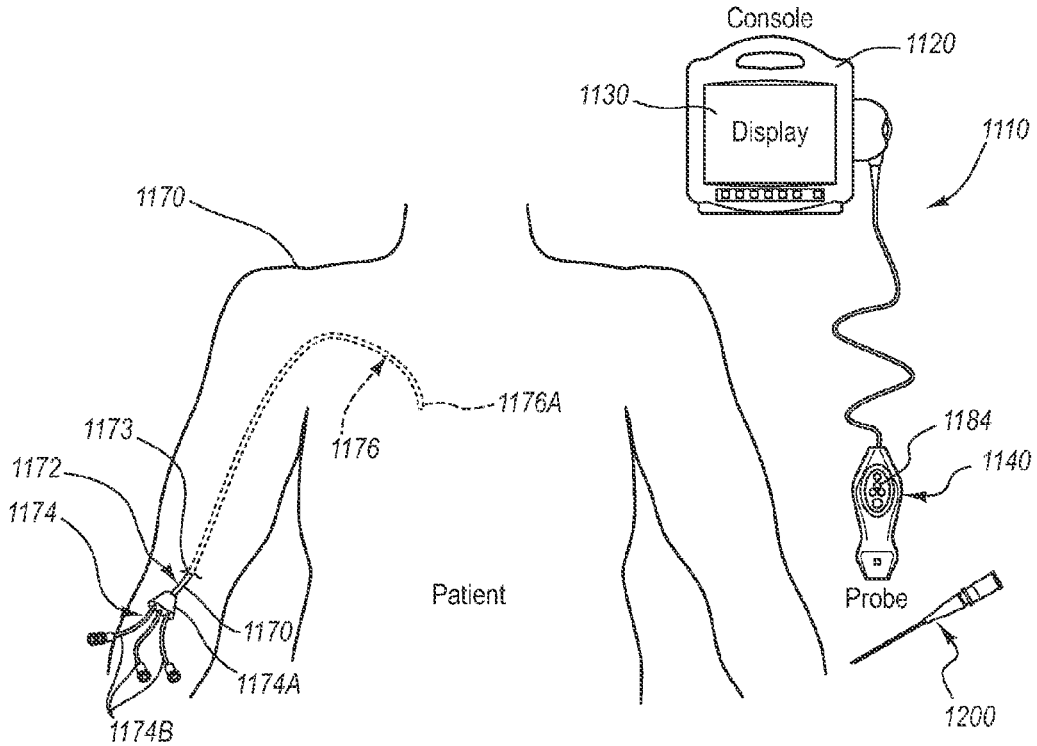
Console
1120
1130
Display
1110
1170
1176A
1173
1176
1184
1172
1140
1174
Patient
Probe
1170
1174A
1200
1174B

FIG. 19

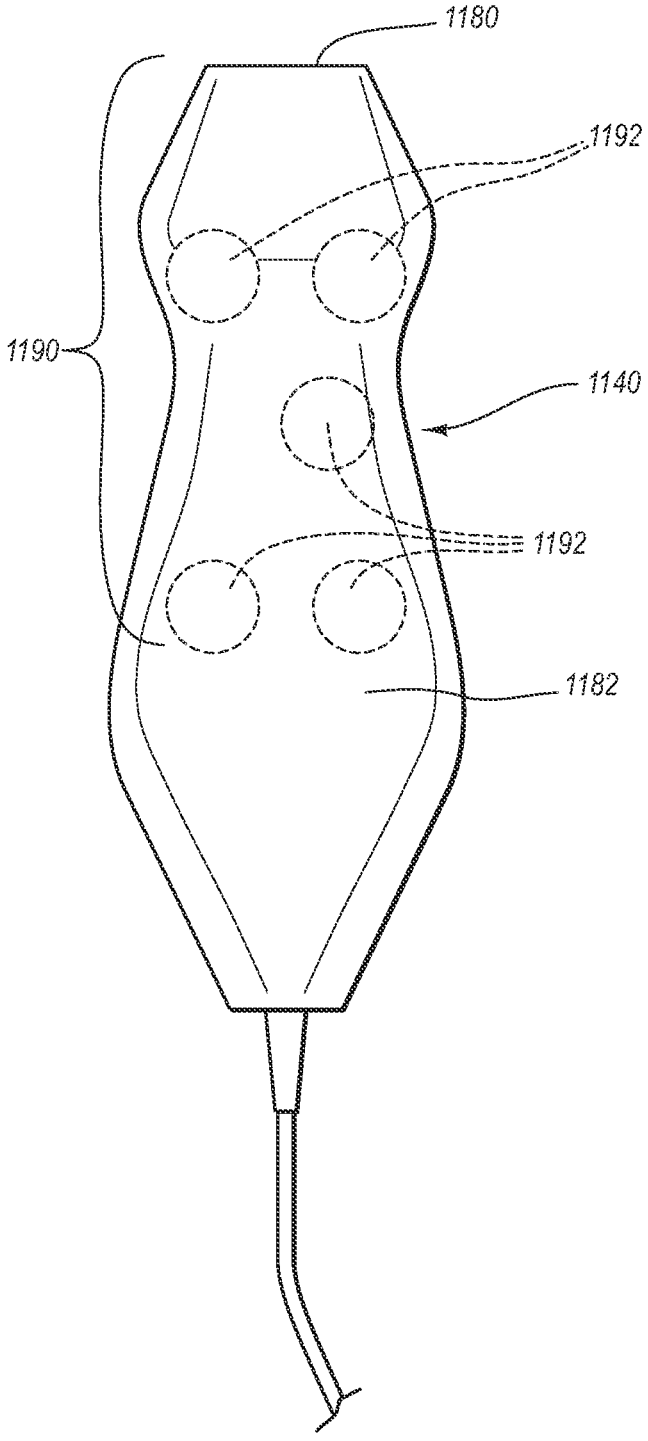

FIG. 20

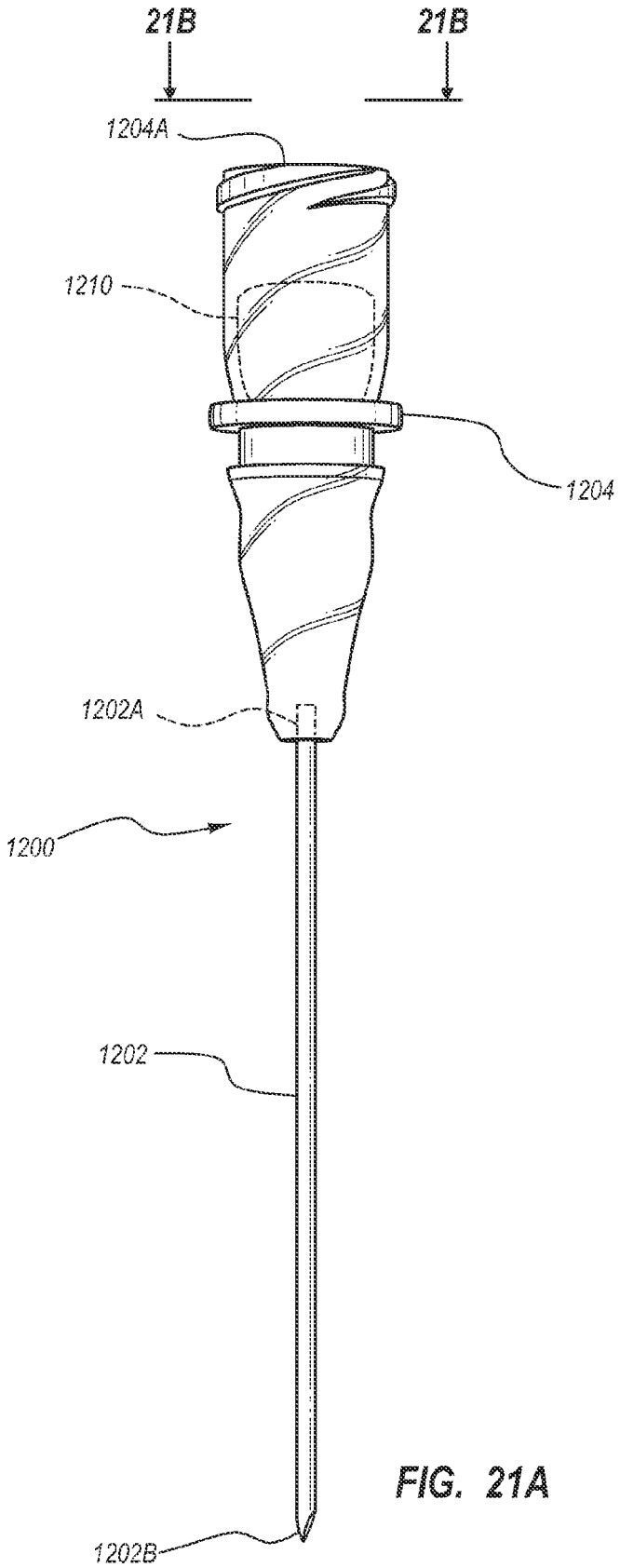

FIG. 21A

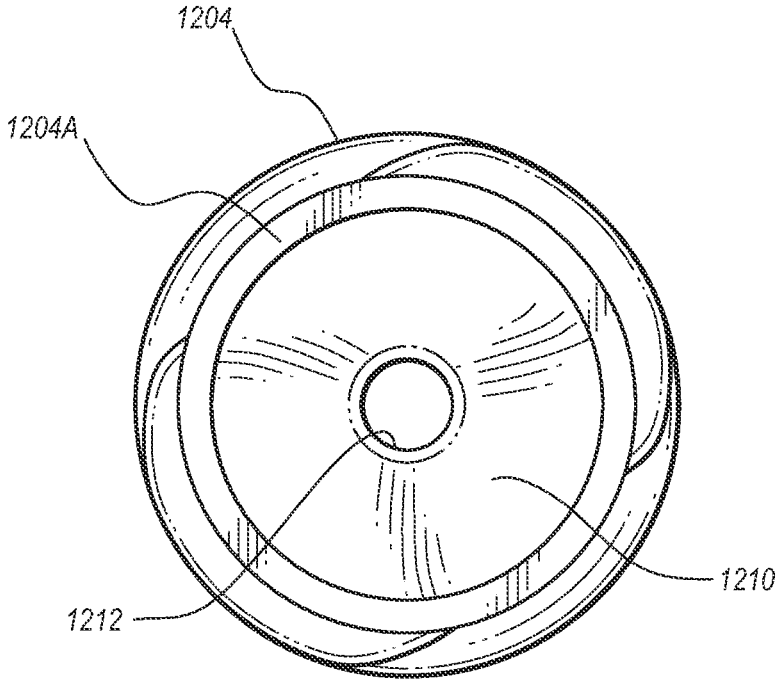

FIG. 21B

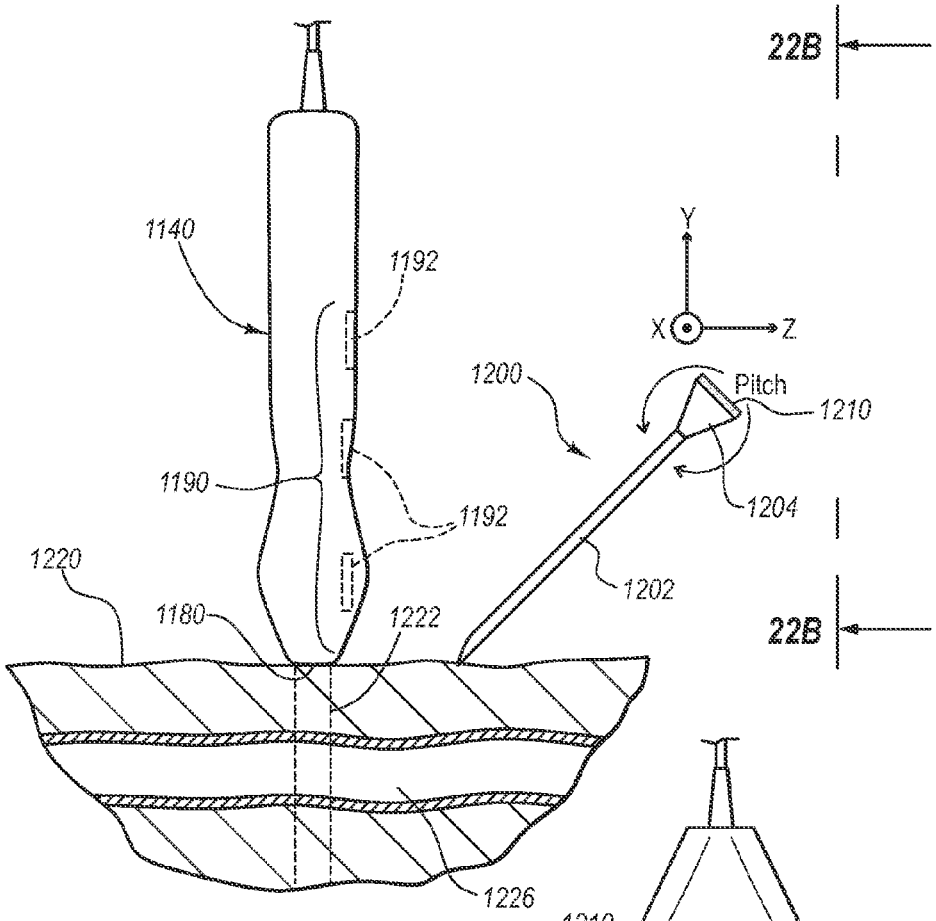

FIG. 22A

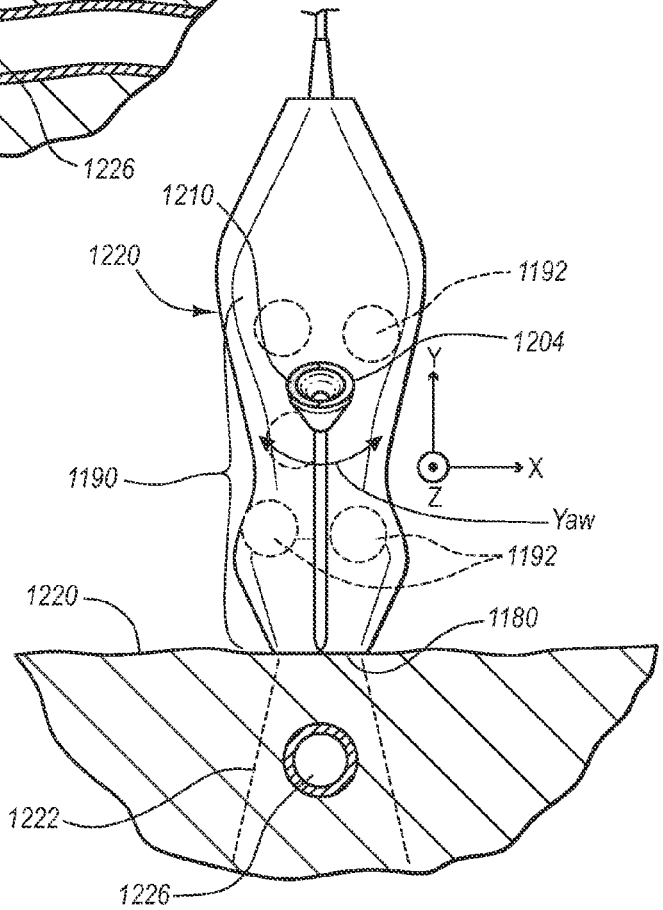

FIG. 22B

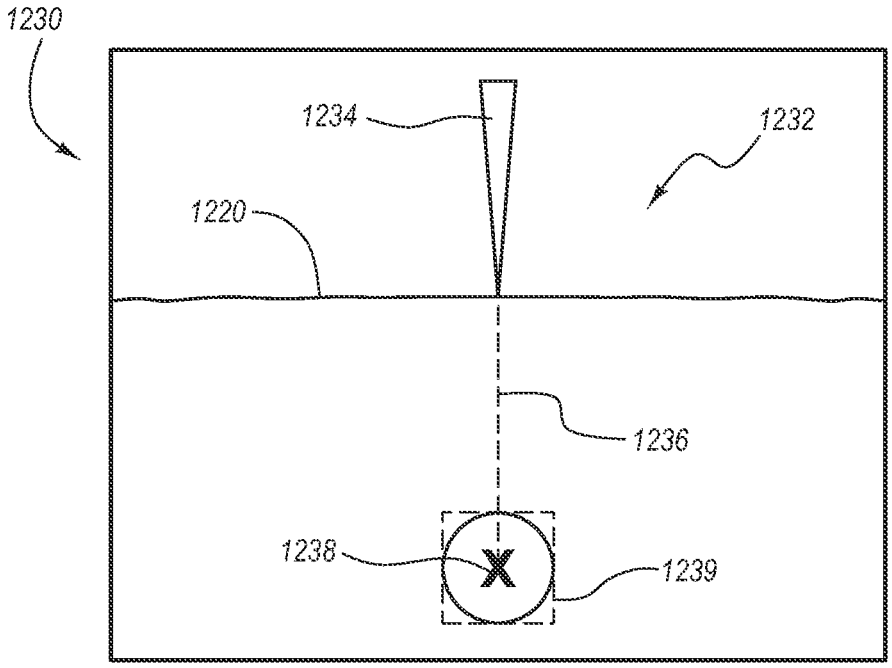

FIG. 23A

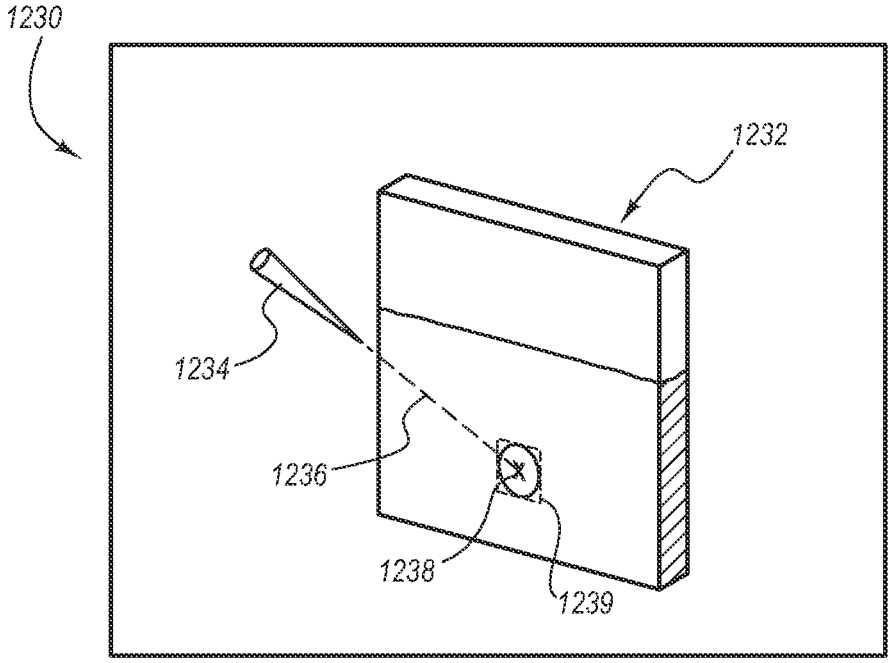

FIG. 23B

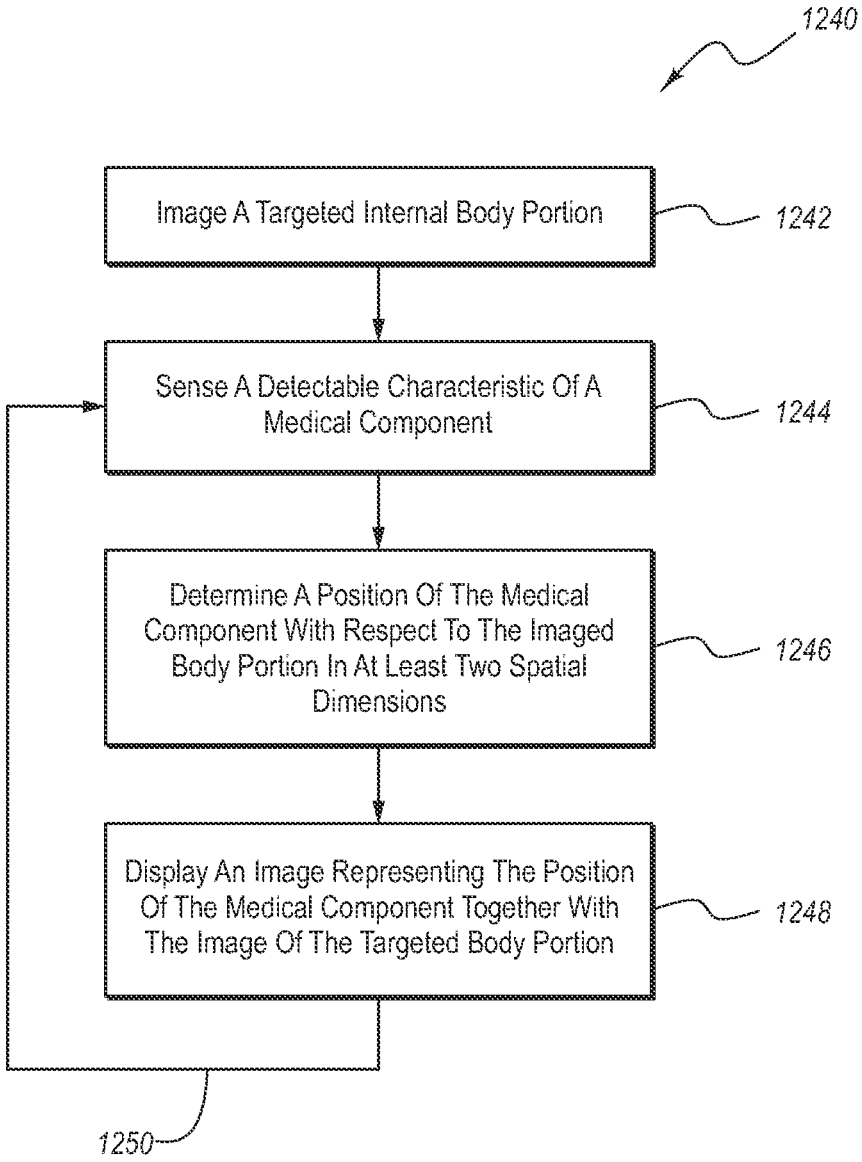
1240
Image A Targeted Internal Body Portion
1242
Sense A Detectable Characteristic Of A Medical Component
1244
Determine A Position Of The Medical Component With Respect To The Imaged Body Portion In At Least Two Spatial Dimensions
1246
Display An Image Representing The Position Of The Medical Component Together With The Image Of The Targeted Body Portion
1248
1250

FIG. 24

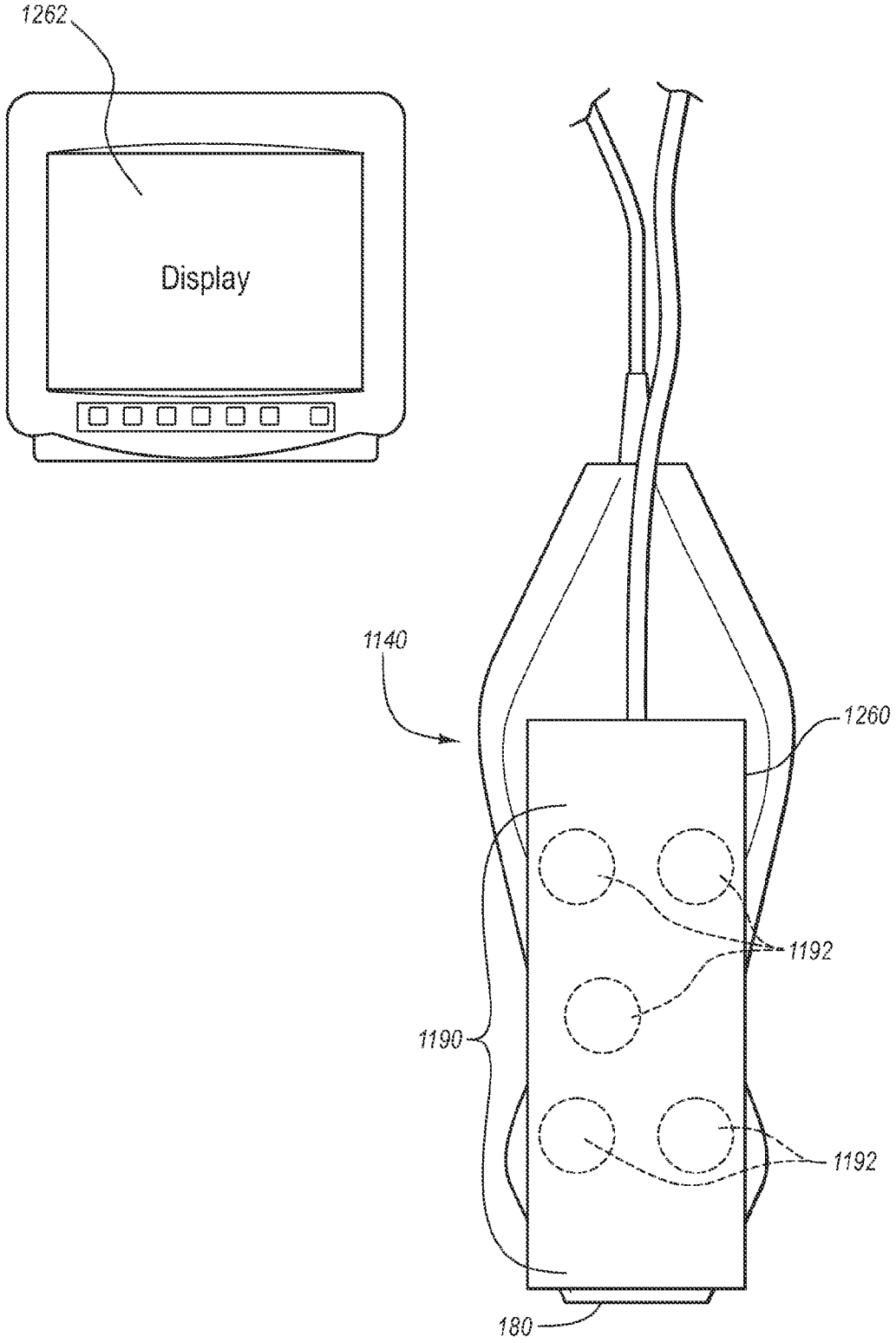

FIG. 25

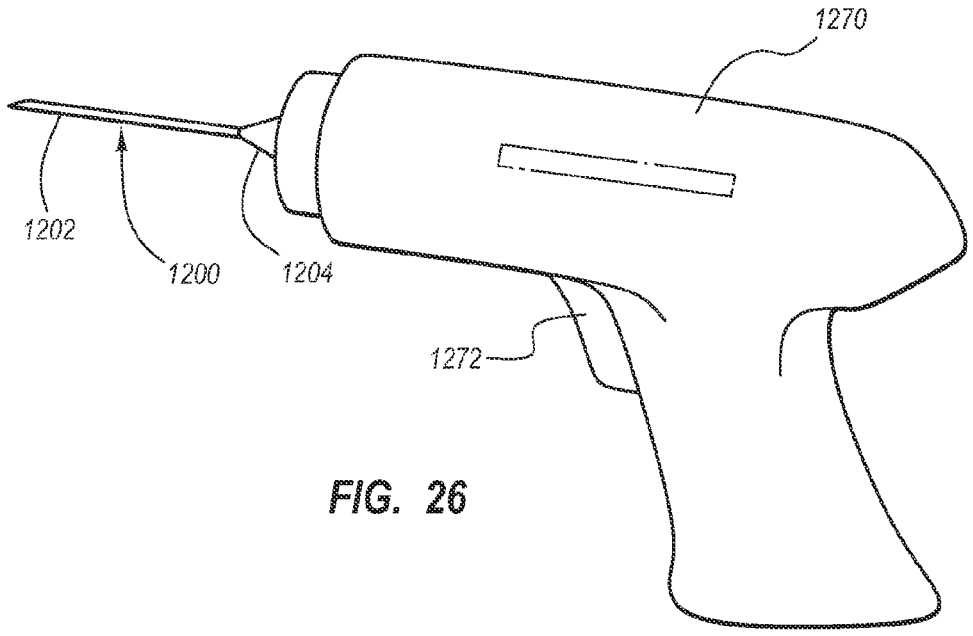
1270
1202
1200
1204
1272

FIG. 26

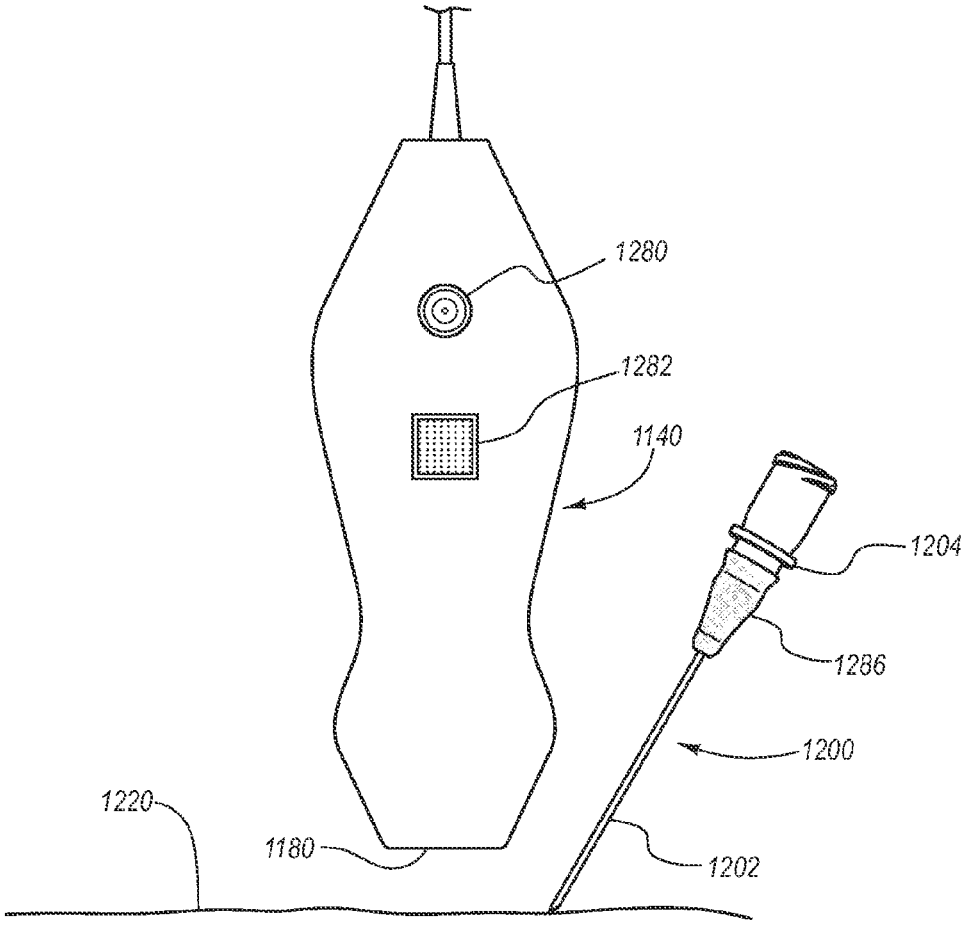
1280
1282
1140
1204
1286
1200
1220
1180
1202

FIG. 27

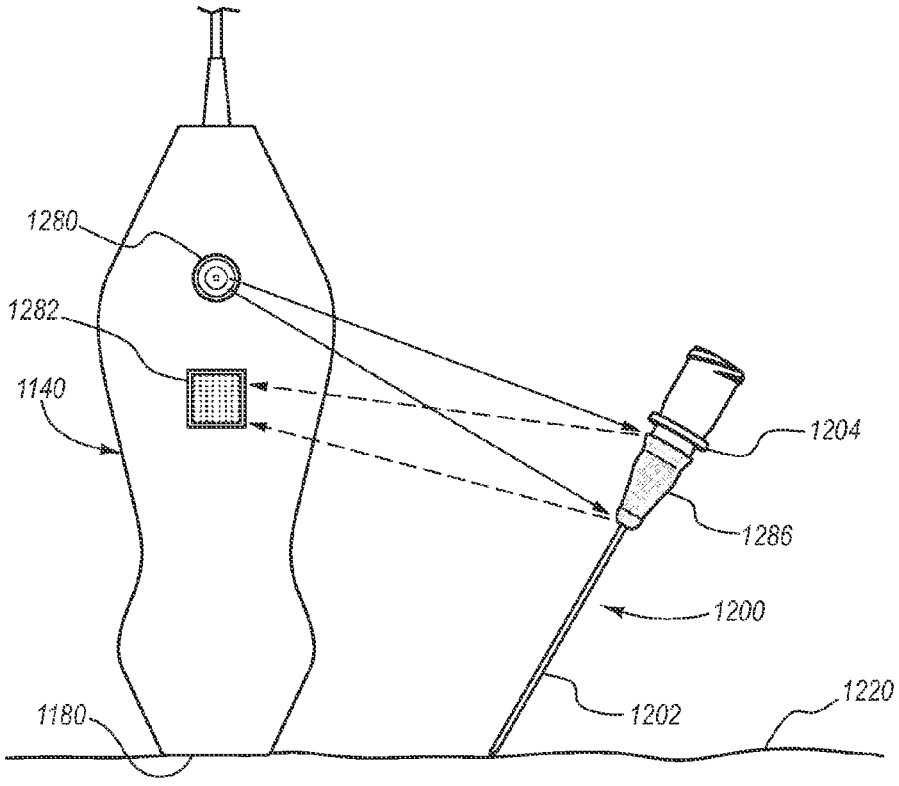
1280
1282
1140
1204
1286
1200
1202
1220
1180

FIG. 28

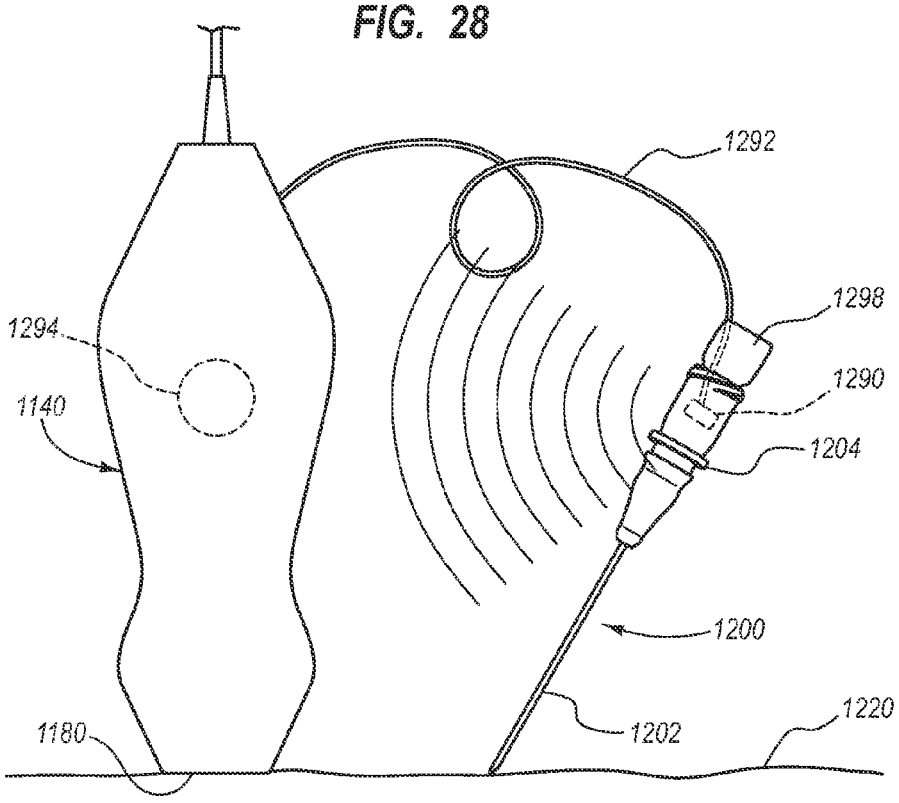
1292
1298
1294
1290
1140
1204
1200
1202
1220
1180

FIG. 29

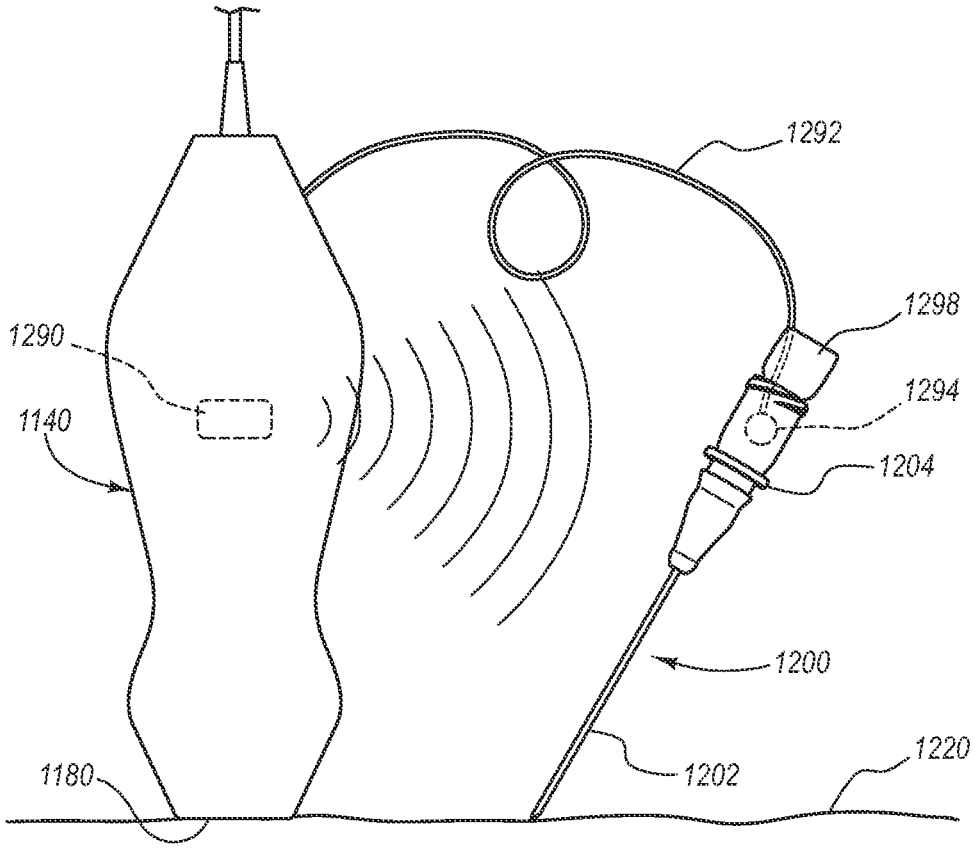

FIG. 30

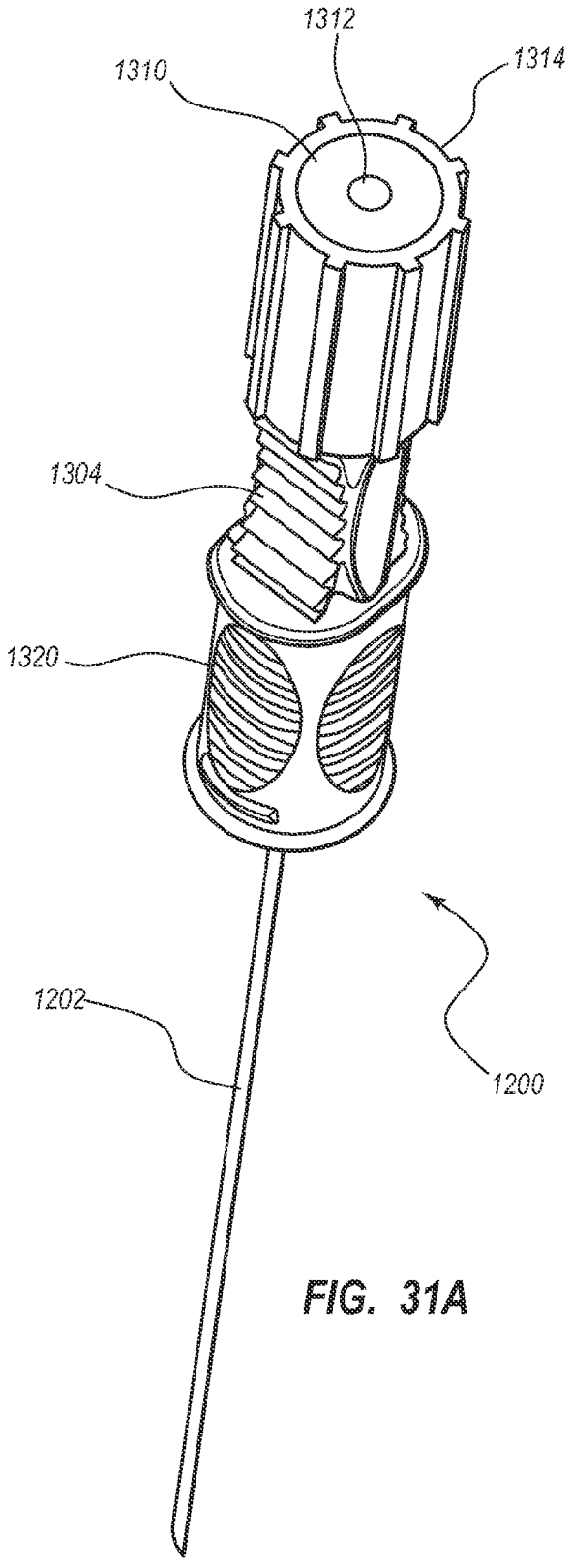

FIG. 31A

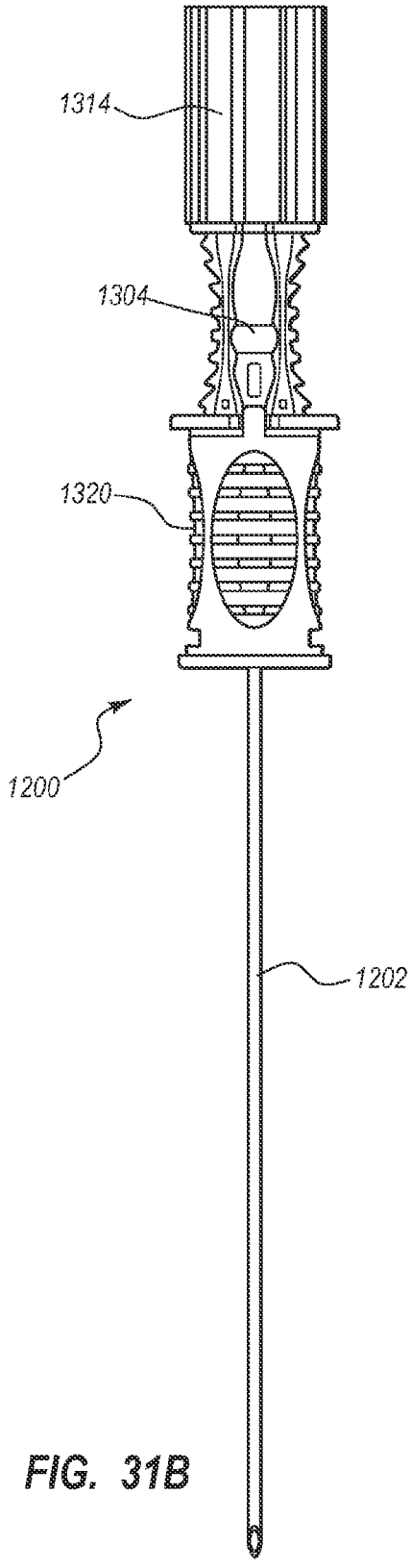

FIG. 31B

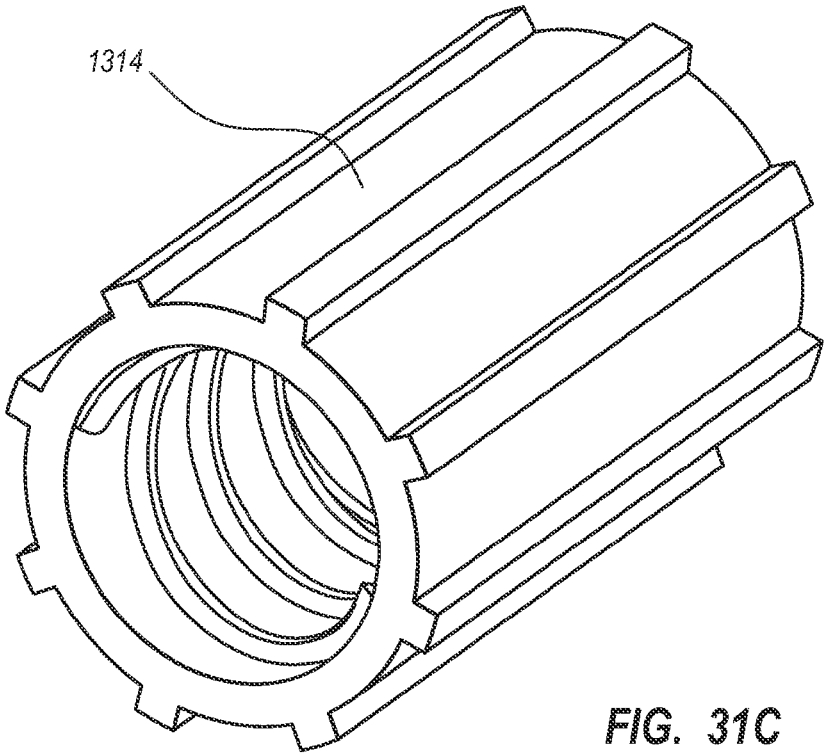

FIG. 31C

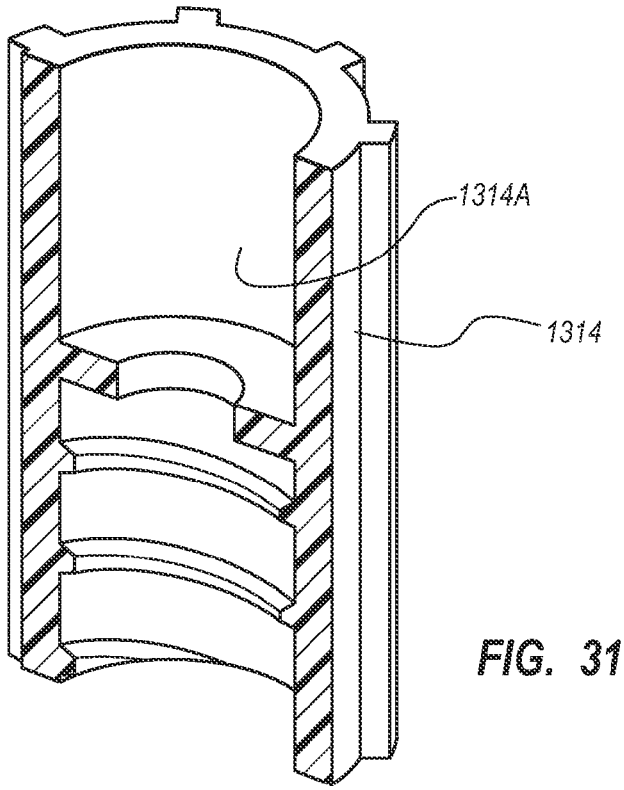

FIG. 31D

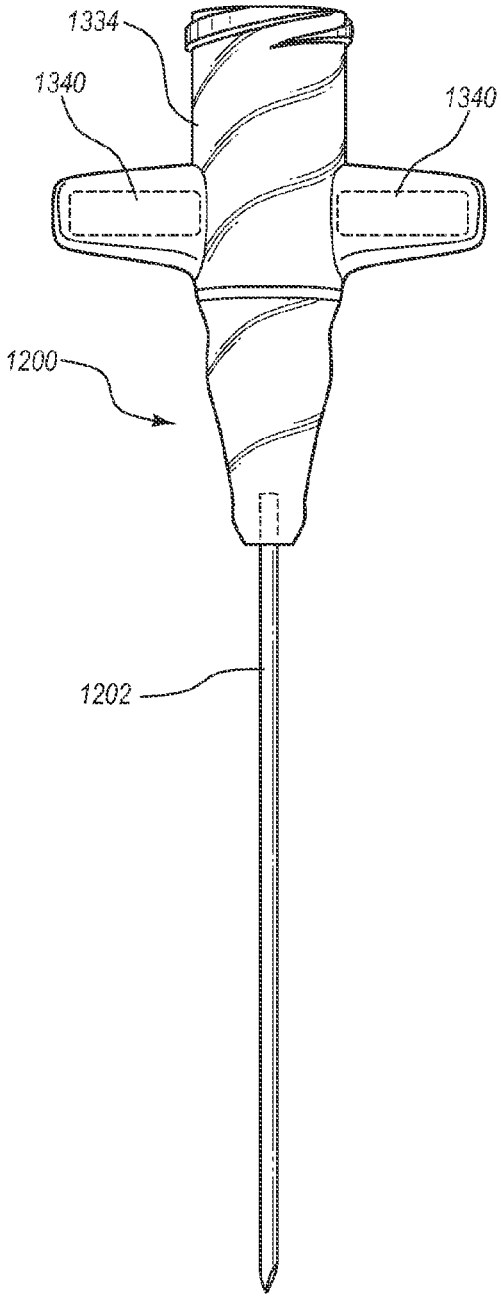

FIG. 32

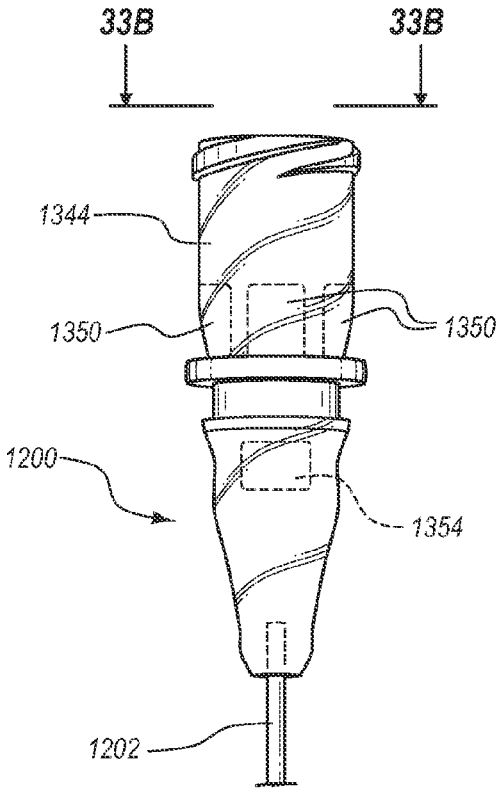

FIG. 33A

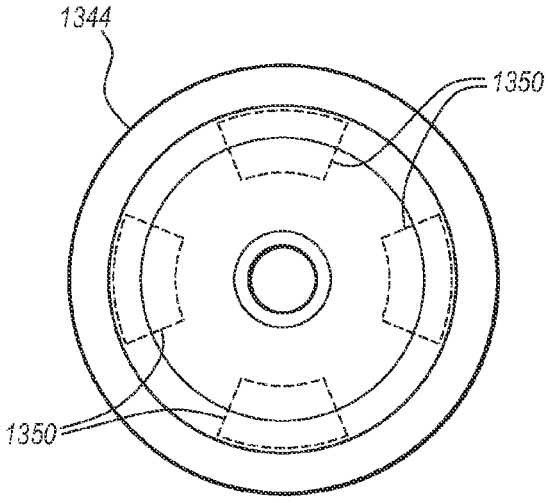

FIG. 33B

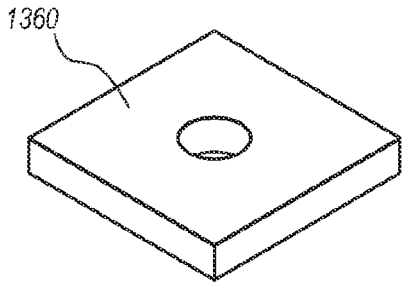

FIG. 34A

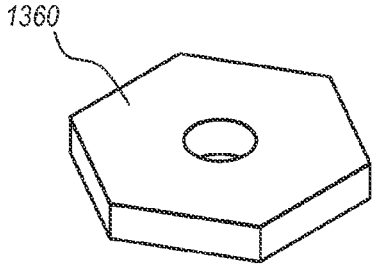

FIG. 34B

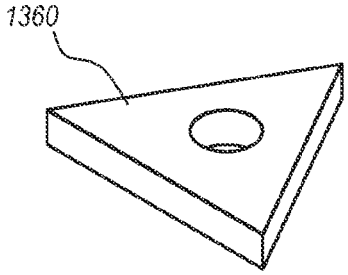

FIG. 34C

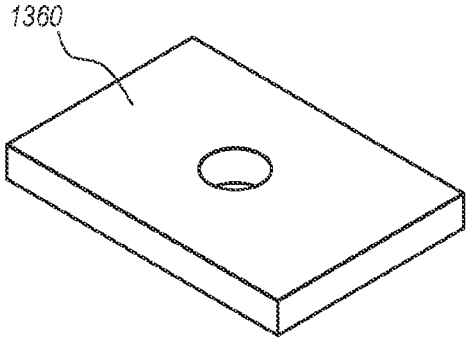

FIG. 34D

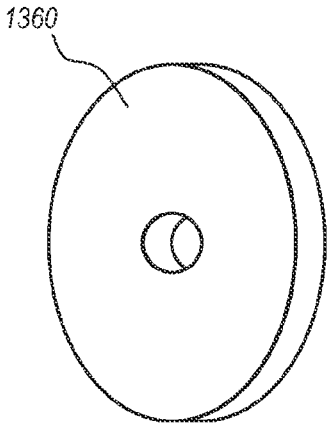

FIG. 34E

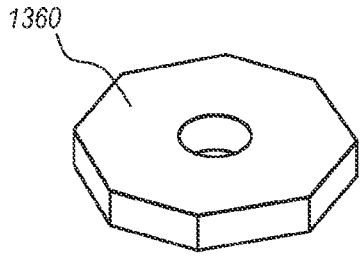

FIG. 34F

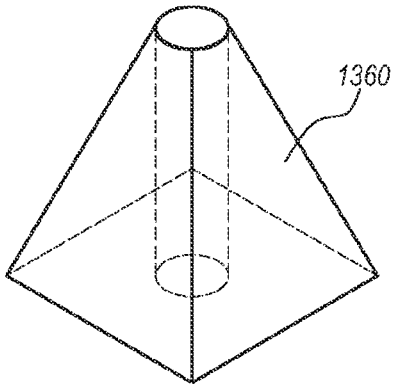

FIG. 34G

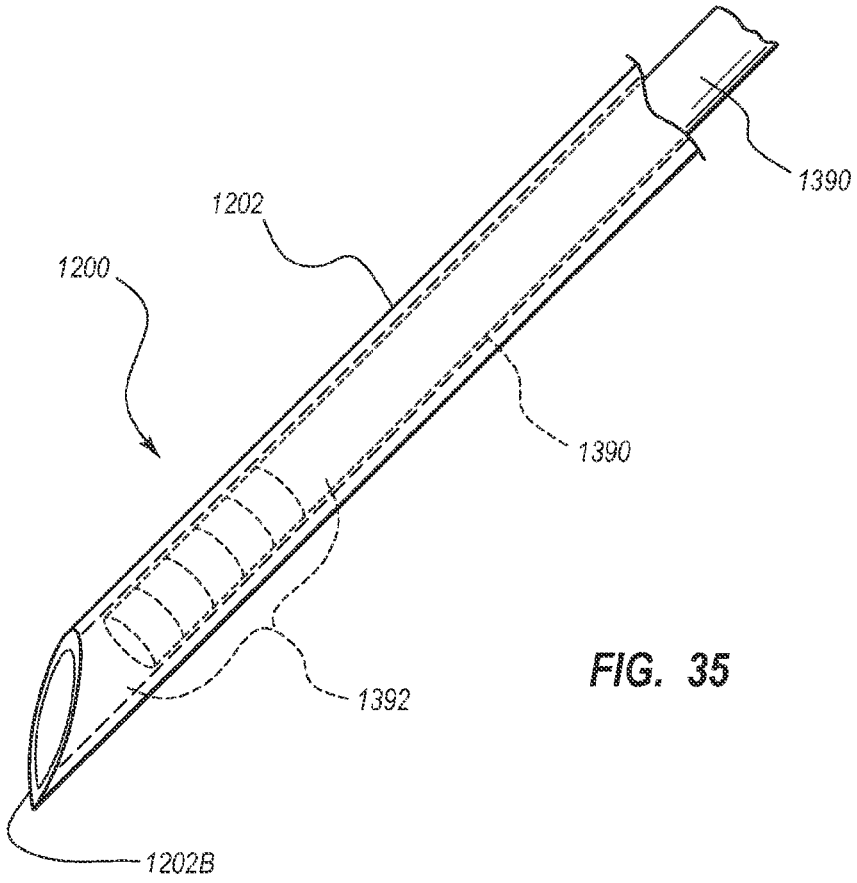
1390
1202
1200
1390
1392
1202B

FIG. 35

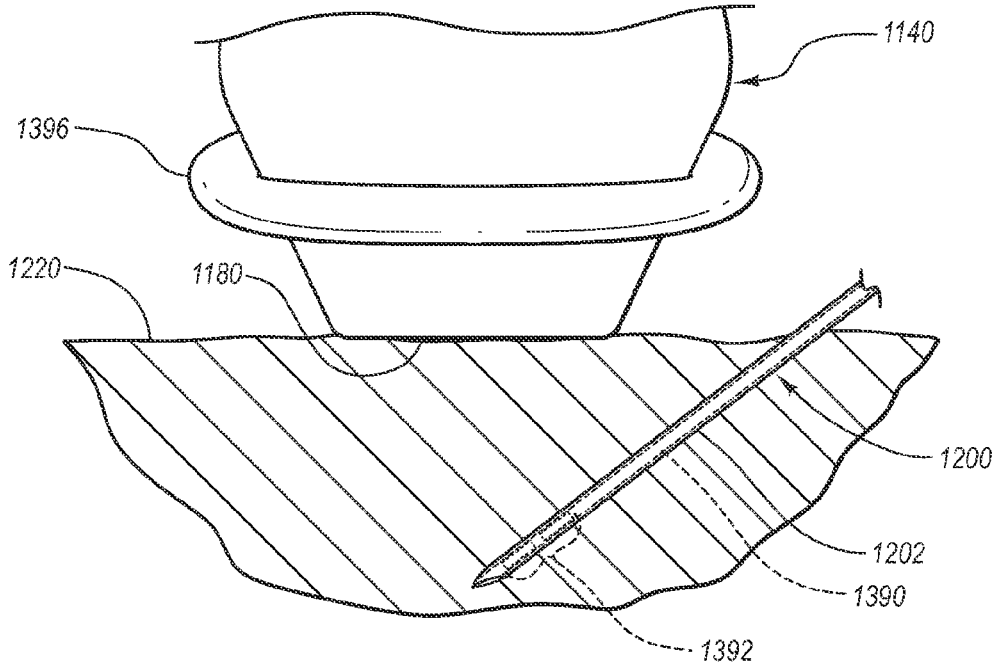
1140
1396
1220
1180
1200
1202
1390
1392

FIG. 36

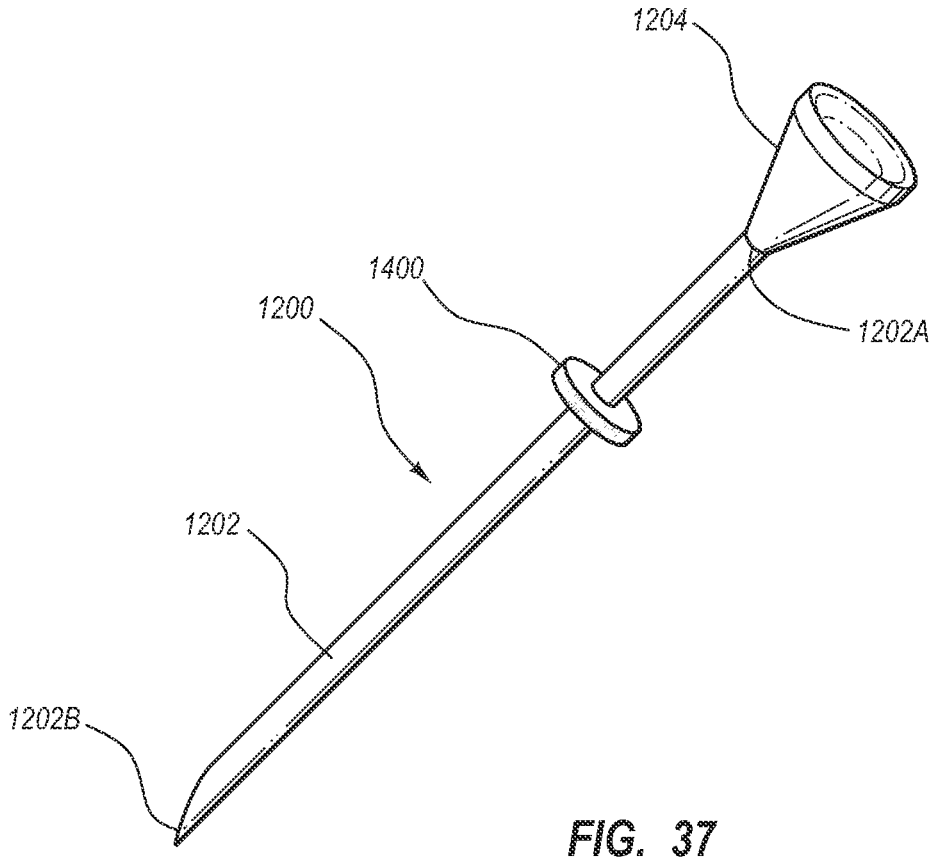

FIG. 37

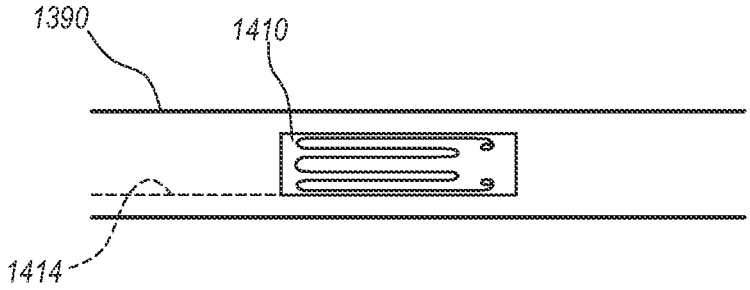

FIG. 38

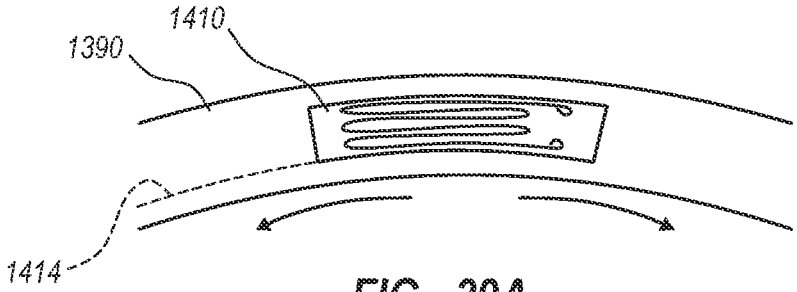

FIG. 39A

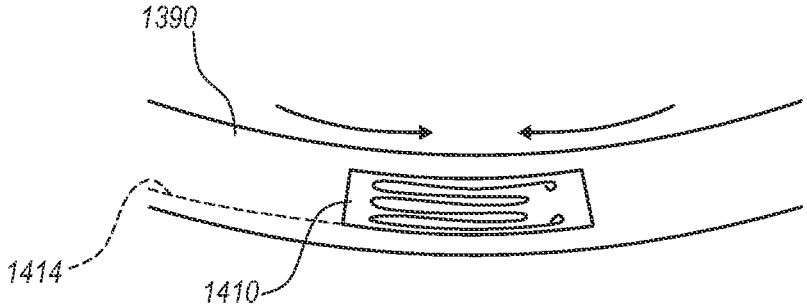

FIG. 39B

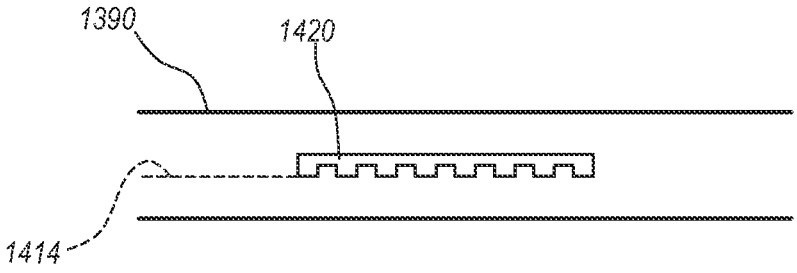

FIG. 40

APPARATUS FOR USE WITH NEEDLE INSERTION GUIDANCE SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of U.S. patent application Ser. No. 13/118,033, filed concurrently herewith and entitled "Insertion Guidance System for Needles and Medical Components," which is a continuation-in-part of U.S. patent application Ser. No. 12/323,273, filed Nov. 25, 2008, and entitled "Integrated System for Intravascular Placement of a Catheter," now U.S. Pat. No. 8,388,541. This application also claims the benefit of U.S. Provisional Patent Application No. 61/349,771, filed May 28, 2010, and entitled "Needle Insertion Guidance System." Each of the aforementioned applications is incorporated herein by reference in its entirety.

BRIEF SUMMARY

Briefly summarized, embodiments of the present invention are directed to an integrated catheter placement system configured for accurately placing a catheter within the vasculature of a patient. The integrated system employs at least two modalities for improving catheter placement accuracy: 1) ultrasound-assisted guidance for introducing the catheter into the patient's vasculature; and 2) a tip location system ("TLS"), or magnetically-based (e.g., via permanent magnet(s) or electromagnet(s)) tracking of the catheter tip during its advancement through the vasculature to detect and facilitate correction of any tip malposition during such advancement.

In one embodiment, the integrated system comprises a system console including a control processor, a tip location sensor for temporary placement on a portion of a body of the patient, and an ultrasound probe. The tip location sensor senses a magnetic field of a stylet disposed in a lumen of the catheter when the catheter is disposed in the vasculature. The ultrasound probe ultrasonically images a portion of the vasculature prior to introduction of the catheter into the vasculature. In addition, the ultrasound probe includes user input controls for controlling use of the ultrasound probe in an ultrasound mode and use of the tip location sensor in a tip location mode.

In another embodiment, a third modality, i.e., ECG signal-based catheter tip guidance, is included in the system to enable guidance of the catheter tip to a desired position with respect to a node of the patient's heart from which the ECG signals originate.

In addition, embodiments of the present disclosure are also directed to a guidance system for assisting with the insertion of a needle or other medical component into the body of a patient. The guidance system utilizes ultrasound imaging or other suitable imaging technology.

In one embodiment, the guidance system comprises an imaging device including a probe for producing an image of an internal body portion target, such as a subcutaneous vessel, for instance. One or more sensors are included with the probe. The sensors sense a detectable characteristic related to the needle, such as a magnetic field of a magnet included with the needle.

The system includes a processor that uses data relating to the detectable characteristic sensed by the sensors to determine a position and/or orientation of the needle in three

spatial dimensions. The system includes a display for depicting the position and/or orientation of the needle together with the image of the target.

In addition to magnet-based detection, other modalities for detecting the medical component are disclosed, including optically-based and electromagnetic signal-based systems.

In one embodiment, a stylet including one or more magnetic elements is removably inserted into the needle to enable tracking of the needle via detection of the magnetic elements by a sensor included with the ultrasound probe. In one embodiment, the sensor is a ring sensor disposed about a portion of the ultrasound probe. In another embodiment, the stylet can additionally include a strain sensor that detects bending of the needle during insertion into the patient. Feedback from the strain sensor can be input into the system and accounted for in order to more accurately depict needle location on the display.

In yet another embodiment, the magnetic element is configured as a donut-shaped passive magnet defining a hole through which the cannula of the needle passes.

These and other features of embodiments of the present invention will become more fully apparent from the following description and appended claims, or may be learned by the practice of embodiments of the invention as set forth hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

A more particular description of the present disclosure will be rendered by reference to specific embodiments thereof that are illustrated in the appended drawings. It is appreciated that these drawings depict only typical embodiments of the invention and are therefore not to be considered limiting of its scope. Example embodiments of the invention will be described and explained with additional specificity and detail through the use of the accompanying drawings in which:

FIG. **1** is a block diagram depicting various elements of an integrated system for intravascular placement of a catheter, according to one example embodiment of the present invention;

FIG. **2** is a simplified view of a patient and a catheter being inserted therein with assistance of the integrated system of FIG. **1**;

FIGS. **3**A and **3**B are views of a probe of the integrated system of FIG. **1**;

FIG. **4** is a screenshot of an ultrasound image as depicted on a display of the integrated system of FIG. **1**;

FIG. **5** is a perspective view of a stylet employed in connection with the system of FIG. **1** in placing a catheter within a patient vasculature;

FIG. **6** is an icon as depicted on a display of the integrated system of FIG. **1**, indicating a position of a distal end of the stylet of FIG. **5** during catheter tip placement procedures;

FIGS. **7**A-**7**E depict various example icons that can be depicted on the display of the integrated system of FIG. **1** during catheter tip placement procedures;

FIGS. **8**A-**8**C are screenshots of images depicted on a display of the integrated system of FIG. **1** during catheter tip placement procedures;

FIG. **9** is a block diagram depicting various elements of an integrated system for intravascular placement of a catheter, according to another example embodiment of the present invention;

FIG. **10** is a simplified view of a patient and a catheter being inserted therein with assistance of the integrated system of FIG. **9**;

FIG. **11** is a perspective view of a stylet employed in connection with the integrated system of FIG. **9** in placing a catheter within a patient vasculature;

FIGS. **12**A-**12**E are various views of portions of the stylet of FIG. **11**;

FIGS. **13**A-**13**D are various views of a fin connector assembly for use with the integrated system of FIG. **9**;

FIGS. **14**A-**14**C are views showing the connection of a stylet tether and fin connector to a sensor of the integrated system of FIG. **9**;

FIG. **15** is a cross sectional view of the connection of the stylet tether, fin connector, and sensor shown in FIG. **14**C;

FIG. **16** is simplified view of an ECG trace of a patient;

FIG. **17** is a screenshot of an image depicted on a display of the integrated system of FIG. **9** during catheter tip placement procedures;

FIG. **18** is a block diagram depicting various elements of an ultrasound-based guidance system for needles and other medical components, according to one embodiment;

FIG. **19** is a simplified view of a patient and a catheter being inserted therein, showing one possible environment in which the guidance system of FIG. **18** can be practiced;

FIG. **20** is a top view of the ultrasound probe of the guidance system of FIG. **18**;

FIG. **21**A is a side view of a needle for use with the guidance system of FIG. **18**, according to one embodiment;

FIG. **21**B is an end view of the needle of FIG. **21**A;

FIGS. **22**A and **22**B are simplified views of the ultrasound probe of the guidance system being used to guide a needle toward a vessel within the body of a patient;

FIGS. **23**A and **23**B show possible screenshots for depiction on the display of the guidance system, showing the position and orientation of a needle according to one embodiment;

FIG. **24** shows various stages of a method for guiding a needle to a desired target within the body of a patient according to one embodiment;

FIG. **25** shows a sensor array for attachment to an ultrasound probe and associated display, according to one embodiment;

FIG. **26** is a simplified view of a needle holder gun for use with the guidance system of FIG. **18**, according to one embodiment;

FIG. **27** is a simplified view of an ultrasound probe and needle including elements of an optical guidance system, according to one embodiment;

FIG. **28** shows operation of the ultrasound probe and needle of FIG. **27**, according to one embodiment;

FIG. **29** is a simplified view of an ultrasound probe and needle including elements of an electromagnetic signal-based guidance system, according to one embodiment;

FIG. **30** is a simplified view of an ultrasound probe and needle including elements of an electromagnetic signal-based guidance system, according to another embodiment;

FIGS. **31**A-**31**D are various views of a needle and associated components for use with a needle guidance system, according to one embodiment;

FIG. **32** is a side view of a needle for use with a needle guidance system, according to one embodiment;

FIGS. **33**A and **33**B are various views of a needle for use with a needle guidance system, according to one embodiment;

FIGS. **34**A-**34**G are views of variously shaped magnetic elements for use with a needle guidance system according to one embodiment;

FIG. **35** is a perspective view of a distal portion of a needle cannula including a magnet-bearing stylet disposed therein, according to one embodiment;

FIG. **36** shows the needle of FIG. **35** in use with an ultrasound probe including a ring sensor, according to one embodiment;

FIG. **37** is a perspective view of a needle including a donut magnet disposed on the cannula, according to one embodiment;

FIG. **38** is a side view of a stylet including a strain gauge according to one embodiment;

FIGS. **39**A-**39**B show the stylet and strain gauge of FIG. **38** under bending stress; and

FIG. **40** is a side view of a stylet including a flex sensor according to one embodiment.

DETAILED DESCRIPTION OF SELECTED EMBODIMENTS

Reference will now be made to figures wherein like structures will be provided with like reference designations. It is understood that the drawings are diagrammatic and schematic representations of exemplary embodiments of the present invention, and are neither limiting nor necessarily drawn to scale.

For clarity it is to be understood that the word "proximal" refers to a direction relatively closer to a clinician using the device to be described herein, while the word "distal" refers to a direction relatively further from the clinician. For example, the end of a needle placed within the body of a patient is considered a distal end of the needle, while the needle end remaining outside the body is a proximal end of the needle. Also, the words "including," "has," and "having," as used herein, including the claims, shall have the same meaning as the word "comprising."

I. Assisted Catheter Placement

Embodiments of the present invention are generally directed to a catheter placement system configured for accurately placing a catheter within the vasculature of a patient. In one embodiment, the catheter placement system employs at least two modalities for improving catheter placement accuracy: 1) ultrasound-assisted guidance for introducing the catheter into the patient's vasculature; and 2) a tip location/navigation system ("TLS"), or magnetically-based tracking of the catheter tip during its advancement through the tortuous vasculature path to detect and facilitate correction of any tip malposition during such advancement. The ultrasound guidance and tip location features of the present system according to one embodiment are integrated into a single device for use by a clinician placing the catheter. Integration of these two modalities into a single device simplifies the catheter placement process and results in relatively faster catheter placements. For instance, the integrated catheter placement system enables ultrasound and TLS activities to be viewed from a single display of the integrated system. Also, controls located on an ultrasound probe of the integrated device, which probe is maintained within the sterile field of the patient during catheter placement, can be used to control functionality of the system, thus precluding the need for a clinician to reach out of the sterile field in order to control the system.

In another embodiment, a third modality, i.e., ECG signal-based catheter tip guidance, is included in the integrated system to enable guidance of the catheter tip to a desired

position with respect to a node of the patient's heart from which the ECG signals originate. Such ECG-based positional assistance is also referred to herein as "tip confirmation."

Combination of the three modalities above according to one embodiment enables the catheter placement system to facilitate catheter placement within the patient's vasculature with a relatively high level of accuracy, i.e., placement of the distal tip of the catheter in a predetermined and desired position. Moreover, because of the ECG-based guidance of the catheter tip, correct tip placement may be confirmed without the need for a confirmatory X-ray. This, in turn, reduces the patient's exposure to potentially harmful x-rays, the cost and time involved in transporting the patient to and from the x-ray department, costly and inconvenient catheter repositioning procedures, etc.

Reference is first made to FIGS. **1** and **2** which depict various components of a catheter placement system ("system"), generally designated at **10**, configured in accordance with one example embodiment of the present invention. As shown, the system **10** generally includes a console **20**, display **30**, probe **40**, and sensor **50**, each of which is described in further detail below.

FIG. **2** shows the general relation of these components to a patient **70** during a procedure to place a catheter **72** into the patient vasculature through a skin insertion site **73**. FIG. **2** shows that the catheter **72** generally includes a proximal portion **74** that remains exterior to the patient and a distal portion **76** that resides within the patient vasculature after placement is complete. The system **10** is employed to ultimately position a distal tip **76**A of the catheter **72** in a desired position within the patient vasculature. In one embodiment, the desired position for the catheter distal tip **76**A is proximate the patient's heart, such as in the lower one-third ($\frac{1}{3}^{rd}$) portion of the Superior Vena Cava ("SVC"). Of course, the system **10** can be employed to place the catheter distal tip in other locations. The catheter proximal portion **74** further includes a hub **74**A that provides fluid communication between the one or more lumens of the catheter **72** and one or more extension legs **74**B extending proximally from the hub.

An example implementation of the console **20** is shown in FIG. **8**C, though it is appreciated that the console can take one of a variety of forms. A processor **22**, including non-volatile memory such as EEPROM for instance, is included in the console **20** for controlling system function during operation of the system **10**, thus acting as a control processor. A digital controller/analog interface **24** is also included with the console **20** and is in communication with both the processor **22** and other system components to govern interfacing between the probe **40**, sensor **50**, and other system components.

The system **10** further includes ports **52** for connection with the sensor **50** and optional components **54** including a printer, storage media, keyboard, etc. The ports in one embodiment are USB ports, though other port types or a combination of port types can be used for this and the other interfaces connections described herein. A power connection **56** is included with the console **20** to enable operable connection to an external power supply **58**. An internal battery **60** can also be employed, either with or exclusive of an external power supply. Power management circuitry **59** is included with the digital controller/analog interface **24** of the console to regulate power use and distribution.

The display **30** in the present embodiment is integrated into the console **20** and is used to display information to the clinician during the catheter placement procedure. In another embodiment, the display may be separate from the console. As will be seen, the content depicted by the display **30** changes according to which mode the catheter placement system is in: US, TLS, or in other embodiments, ECG tip confirmation. In one embodiment, a console button interface **32** (see FIGS. **1**, **8**C) and buttons included on the probe **40** can be used to immediately call up a desired mode to the display **30** by the clinician to assist in the placement procedure. In one embodiment, information from multiple modes, such as TLS and ECG, may be displayed simultaneously, such as in FIG. **17**. Thus, the single display **30** of the system console **20** can be employed for ultrasound guidance in accessing a patient's vasculature, TLS guidance during catheter advancement through the vasculature, and (as in later embodiments) ECG-based confirmation of catheter distal tip placement with respect to a node of the patient's heart. In one embodiment, the display **30** is an LCD device.

FIGS. **3**A and **3**B depict features of the probe **40** according to one embodiment. The probe **40** is employed in connection with the first modality mentioned above, i.e., ultrasound ("US")-based visualization of a vessel, such as a vein, in preparation for insertion of the catheter **72** into the vasculature. Such visualization gives real time ultrasound guidance for introducing the catheter into the vasculature of the patient and assists in reducing complications typically associated with such introduction, including inadvertent arterial puncture, hematoma, pneumothorax, etc.

The handheld probe **40** includes a head **80** that houses a piezoelectric array for producing ultrasonic pulses and for receiving echoes thereof after reflection by the patient's body when the head is placed against the patient's skin proximate the prospective insertion site **73** (FIG. **2**). The probe **40** further includes a plurality of control buttons **84**, which can be included on a button pad **82**. In the present embodiment, the modality of the system **10** can be controlled by the control buttons **84**, thus eliminating the need for the clinician to reach out of the sterile field, which is established about the patient insertion site prior to catheter placement, to change modes via use of the console button interface **32**.

As such, in one embodiment a clinician employs the first (US) modality to determine a suitable insertion site and establish vascular access, such as with a needle or introducer, then with the catheter. The clinician can then seamlessly switch, via button pushes on the probe button pad **82**, to the second (TLS) modality without having to reach out of the sterile field. The TLS mode can then be used to assist in advancement of the catheter **72** through the vasculature toward an intended destination.

FIG. **1** shows that the probe **40** further includes button and memory controller **42** for governing button and probe operation. The button and memory controller **42** can include non-volatile memory, such as EEPROM, in one embodiment. The button and memory controller **42** is in operable communication with a probe interface **44** of the console **20**, which includes a piezo input/output component **44**A for interfacing with the probe piezoelectric array and a button and memory input/output component **44**B for interfacing with the button and memory controller **42**.

FIG. **4** shows an example screenshot **88** as depicted on the display **30** while the system **10** is in its first ultrasound modality. An image **90** of a subcutaneous region of the patient **70** is shown, depicting a cross section of a vein **92**. The image **90** is produced by operation of the piezoelectric array of the probe **40**. also included on the display screenshot **88** is a depth scale indicator **94**, providing information

regarding the depth of the image **90** below the patient's skin, a lumen size scale **96** that provides information as to the size of the vein **92** relative to standard catheter lumen sizes, and other indicia **98** that provide information regarding status of the system **10** or possible actions to be taken, e.g., freeze frame, image templates, data save, image print, power status, image brightness, etc.

Note that while a vein is depicted in the image **90**, other body lumens or portions can be imaged in other embodiments. Note that the US mode shown in FIG. **4** can be simultaneously depicted on the display **30** with other modes, such as the TLS mode, if desired. In addition to the visual display **30**, aural information, such as beeps, tones, etc., can also be employed by the system **10** to assist the clinician during catheter placement. Moreover, the buttons included on the probe **40** and the console button interface **32** can be configured in a variety of ways, including the use of user input controls in addition to buttons, such as slide switches, toggle switches, electronic or touch-sensitive pads, etc. Additionally, both US and TLS activities can occur simultaneously or exclusively during use of the system **10**.

As just described, the handheld ultrasound probe **40** is employed as part of the integrated catheter placement system **10** to enable US visualization of the peripheral vasculature of a patient in preparation for transcutaneous introduction of the catheter. In the present example embodiment, however, the probe is also employed to control functionality of the TLS portion, or second modality, of the system **10** when navigating the catheter toward its desired destination within the vasculature as described below. Again, as the probe **40** is used within the sterile field of the patient, this feature enables TLS functionality to be controlled entirely from within the sterile field. Thus the probe **40** is a dual-purpose device, enabling convenient control of both US and TLS functionality of the system **10** from the sterile field. In one embodiment, the probe can also be employed to control some or all ECG-related functionality, or third modality, of the catheter placement system **10**, as described further below.

The catheter placement system **10** further includes the second modality mentioned above, i.e., the magnetically-based catheter TLS, or tip location system. The TLS enables the clinician to quickly locate and confirm the position and/or orientation of the catheter **72**, such as a peripherally-inserted central catheter ("PICC"), central venous catheter ("CVC"), or other suitable catheter, during initial placement into and advancement through the vasculature of the patient **70**. Specifically, the TLS modality detects a magnetic field generated by a magnetic element-equipped tip location stylet, which is pre-loaded in one embodiment into a longitudinally defined lumen of the catheter **72**, thus enabling the clinician to ascertain the general location and orientation of the catheter tip within the patient body. In one embodiment, the magnetic assembly can be tracked using the teachings of one or more of the following U.S. Pat. Nos. 5,775,322; 5,879,297; 6,129,668; 6,216,028; and 6,263,230. The contents of the afore-mentioned U.S. patents are incorporated herein by reference in their entireties. The TLS also displays the direction in which the catheter tip is pointing, thus further assisting accurate catheter placement. The TLS further assists the clinician in determining when a malposition of the catheter tip has occurred, such as in the case where the tip has deviated from a desired venous path into another vein.

As mentioned, the TLS utilizes a stylet to enable the distal end of the catheter **72** to be tracked during its advancement through the vasculature. FIG. **5** gives an example of such a stylet **100**, which includes a proximal end **100**A and a distal end **100**B. A handle is included at the stylet proximal end **100**A, with a core wire **104** extending distally therefrom. A magnetic assembly is disposed distally of the core wire **104**. The magnetic assembly includes one or more magnetic elements **106** disposed adjacent one another proximate the stylet distal end **100**B and encapsulated by tubing **108**. In the present embodiment, a plurality of magnetic elements **106** is included, each element including a solid, cylindrically shaped ferromagnetic stacked end-to-end with the other magnetic elements. An adhesive tip **110** can fill the distal tip of the tubing **108**, distally to the magnetic elements **106**.

Note that in other embodiments, the magnetic elements may vary from the design in not only shape, but also composition, number, size, magnetic type, and position in the stylet distal segment. For example, in one embodiment, the plurality of ferromagnetic magnetic elements is replaced with an electromagnetic assembly, such as an electromagnetic coil, which produces a magnetic field for detection by the sensor. Another example of an assembly usable here can be found in U.S. Pat. No. 5,099,845 entitled "Medical Instrument Location Means," which is incorporated herein by reference in its entirety. Yet other examples of stylets including magnetic elements that can be employed with the TLS modality can be found in U.S. Publication No. 2007/0049846, filed Aug. 23, 2006, and entitled "Stylet Apparatuses and Methods of Manufacture," which is incorporated herein by reference in its entirety. These and other variations are therefore contemplated by embodiments of the present invention. It should appreciated herein that "stylet" as used herein can include any one of a variety of devices configured for removable placement within a lumen of the catheter to assist in placing a distal end of the catheter in a desired location within the patient's vasculature.

FIG. **2** shows disposal of the stylet **100** substantially within a lumen in the catheter **72** such that the proximal portion thereof extends proximally from the catheter lumen, through the hub **74**A and out through a selected one of the extension legs **74**B. So disposed within a lumen of the catheter, the distal end **100**B of the stylet **100** is substantially co-terminal with the distal catheter end **76**A such that detection by the TLS of the stylet distal end correspondingly indicates the location of the catheter distal end.

The TLS sensor **50** is employed by the system **10** during TLS operation to detect a magnetic field produced by the magnetic elements **106** of the stylet **100**. As seen in FIG. **2**, the TLS sensor **50** is placed on the chest of the patient during catheter insertion. The TLS sensor **50** is placed on the chest of the patient in a predetermined location, such as through the use of external body landmarks, to enable the magnetic field of the stylet magnetic elements **106**, disposed in the catheter **72** as described above, to be detected during catheter transit through the patient vasculature. Again, as the magnetic elements **106** of the stylet magnetic assembly are co-terminal with the distal end **76**A of the catheter **72** (FIG. **2**), detection by the TLS sensor **50** of the magnetic field of the magnetic elements provides information to the clinician as to the position and orientation of the catheter distal end during its transit.

In greater detail, the TLS sensor **50** is operably connected to the console **20** of the system **10** via one or more of the ports **52**, as shown in FIG. **1**. Note that other connection schemes between the TLS sensor and the system console can also be used without limitation. As just described, the magnetic elements **106** are employed in the stylet **100** to enable the position of the catheter distal end **76**A (FIG. **2**) to be observable relative to the TLS sensor **50** placed on the

patient's chest. Detection by the TLS sensor **50** of the stylet magnetic elements **106** is graphically displayed on the display **30** of the console **20** during TLS mode. In this way, a clinician placing the catheter is able to generally determine the location of the catheter distal end **76**A within the patient vasculature relative o the TLS sensor **50** and detect when catheter malposition, such as advancement of the catheter along an undesired vein, is occurring.

FIGS. **6** and **7**A-**7**E show examples of icons that can be used by the console display **30** to depict detection of the stylet magnetic elements **106** by the TLS sensor **50**. In particular, FIG. **6** shows an icon **114** that depicts the distal portion of the stylet **100**, including the magnetic elements **106** as detected by the TLS sensor **50** when the magnetic elements are positioned under the TLS sensor. As the stylet distal end **100**B is substantially co-terminal with the distal end **76**A of the catheter **72**, the icon indicates the position and orientation of the catheter distal end. FIGS. **7**A-**7**E show various icons that can be depicted on the on the console display **30** when the magnetic elements **106** of the stylet **100** are not positioned directly under a portion of the TLS sensor **50**, but are nonetheless detected nearby. The icons can include half-icons **114**A and quarter-icons **114**B that are displayed according to the position of the stylet magnetic assembly, i.e., the magnetic elements **106** in the present embodiment, relative to the TLS sensor **50**.

FIGS. **8**A-**8**C depict screenshots taken from the display **30** of the system **10** while in TLS mode, showing how the magnetic assembly of the stylet **100** is depicted. The screenshot **118** of FIG. **8**A shows a representative image **120** of the TLS sensor **50**. Other information is provided on the display screenshot **118**, including a depth scale indicator **124**, status/action indicia **126**, and icons **128** corresponding to the button interface **32** included on the console **20** (FIG. **8**C). Though the icons **128** in the present embodiment are simply indicators to guide the user in identifying the purpose of the corresponding buttons of the button interface **32**, in another embodiment the display can be made touch-sensitive so that the icons themselves can function as button interfaces and can change according to the mode the system is in.

During initial stages of catheter advancement through the patient's vasculature after insertion therein, the distal end **76**A of the catheter **72**, having the stylet distal end **100**B substantially co-terminal therewith, is relatively distant from the TLS sensor **50**. As such, the display screenshot will indicate "no signal," indicating that the magnetic field from the stylet magnetic assembly has not been detected. In FIG. **8**B, the magnetic assembly proximate the stylet distal end **100**B has advanced sufficiently close to the TLS sensor **50** to be detected thereby, though it is not yet under the sensor. This is indicated by the half-icon **114**A shown to the left of the sensor image **120**, representing the stylet magnetic assembly being positioned to the right of the TLS sensor **50** from the perspective of the patient.

In FIG. **8**C, the magnetic assembly proximate the stylet distal end **100**B has advanced under the TLS sensor **50** such that its position and orientation relative thereto is detected by the TLS sensor. This is indicated by the icon **114** on the sensor image **120**. Note that the button icons **128** provide indications of the actions that can be performed by pressing the corresponding buttons of the console button interface **32**. As such, the button icons **128** can change according to which modality the system **10** is in, thus providing flexibility of use for the button interface **32**. Note further that, as the button pad **82** of the probe **40** (FIG. **3**A, **3**B) includes buttons **84** that mimic several of the buttons of the button interface **32**, the button icons **128** on the display **30** provide a guide to the clinician for controlling the system **10** with the probe buttons **84** while remaining in the sterile field. For instance, if the clinician has need to leave TLS mode and return to US (ultrasound) mode, the appropriate control button **84** on the probe button pad **82** can be depressed, and the US mode can be immediately called up, with the display **30** refreshing to accommodate the visual information needed for US functionality, such as that shown in FIG. **4**. This is accomplished without a need for the clinician to reach out of the sterile field.

Reference is now made to FIGS. **9** and **10** in describing the integrated catheter placement system **10** according to another example embodiment. As before, the integrated system **10** includes the console **20**, display **30**, probe **40** for US functionality, and the TLS sensor **50** for tip location functionality as described above. Note that the system **10** depicted in FIGS. **9** and **10** is similar in many respects to the system shown in FIGS. **1** and **2**. As such, only selected differences will be discussed below. The system **10** of FIGS. **9** and **10** includes additional functionality wherein determination of the proximity of the catheter distal tip **76**A relative to a sino-atrial ("SA") or other electrical impulse-emitting node of the heart of the patient **70** can be determined, thus providing enhanced ability to accurately place the catheter distal tip in a desired location proximate the node. Also referred to herein as "ECG" or "ECG-based tip confirmation," this third modality of the system **10** enables detection of ECG signals from the SA node in order to place the catheter distal tip in a desired location within the patient vasculature. Note that the US, TLS, and ECG modalities are seamlessly combined in the present system **10** and can be employed in concert or individually to assist in catheter placement.

FIGS. **9** and **10** show the addition to the system **10** of a stylet **130** configured in accordance with the present embodiment. As an overview, the catheter stylet **130** is removably predisposed within the lumen of the catheter **72** being inserted into the patient **70** via the insertion site **73**. The stylet **130**, in addition to including a magnetic assembly for the magnetically-based TLS modality, includes an ECG sensor assembly proximate its distal end and including a portion that is co-terminal with the distal end of the catheter tip for sensing ECG signals produced by the SA node. In contrast to the previous embodiment, the stylet **130** includes a tether **134** extending from its proximal end that operably connects to the TLS sensor **50**. As will be described in further detail, the stylet tether **134** permits ECG signals detected by the ECG sensor assembly included on a distal portion of the stylet **130** to be conveyed to the TLS sensor **50** during confirmation of the catheter tip location as part of the ECG signal-based tip confirmation modality. Reference and ground ECG lead/electrode pairs **158** attach to the body of the body of the patient **70** and are operably attached to the TLS sensor **50** to enable the system to filter out high level electrical activity unrelated to the electrical activity of the SA node of the heart, thus enabling the ECG-based tip confirmation functionality. Together with the reference and ground signals received from the ECG lead/electrode pairs **158** placed on the patient's skin, the ECG signals sensed by the stylet ECG sensor assembly are received by the TLS sensor **50** positioned on the patient's chest (FIG. **10**). The TLS sensor **50** and/or console processor **22** can process the ECG signal data to produce an electrocardiogram waveform on the display **30**, as will be described. In the case where the TLS sensor **50** processes the ECG signal data, a processor is included therein to perform the intended functionality. If the

console **20** processes the ECG signal data, the processor **22**, controller **24**, or other processor can be utilized in the console to process the data.

Thus, as it is advanced through the patient vasculature, the catheter **72** equipped with the stylet **130** as described above can advance under the TLS sensor **50**, which is positioned on the chest of the patient as shown in FIG. **10**. This enables the TLS sensor **50** to detect the position of the magnetic assembly of the stylet **130**, which is substantially co-terminal with the distal tip **76**A of the catheter as located within the patient's vasculature. The detection by the TLS sensor **50** of the stylet magnetic assembly is depicted on the display **30** during ECG mode. The display **30** further depicts during ECG mode an ECG electrocardiogram waveform produced as a result of patient heart's electrical activity as detected by the ECG sensor assembly of the stylet **130**. In greater detail, the ECG electrical activity of the SA node, including the P-wave of the waveform, is detected by the ECG sensor assembly of the stylet (described below) and forwarded to the TLS sensor **50** and console **20**. The ECG electrical activity is then processed for depiction on the display **30**. clinician placing the catheter can then observe the ECG data to determine optimum placement of the distal tip **76**A of the catheter **72**, such as proximate the SA node in one embodiment. In one embodiment, the console **20** which includes the electronic components, such as the processor **22** (FIG. **9**) necessary to receive and process the signals detected by the stylet ECG sensor assembly. In another embodiment, the TLS sensor **50** can include the necessary electronic components processing the ECG signals.

As already discussed, the display **30** is used to display information to the clinician during the catheter placement procedure. The content of the display **30** changes according to which mode the catheter placement system is in: US, TLS, or ECG. Any of the three modes can be immediately called up to the display **30** by the clinician, and in some cases information from multiple modes, such as TLS and ECG, may be displayed simultaneously. In one embodiment, as before, the mode the system is in may be controlled by the control buttons **84** included on the handheld probe **40**, thus eliminating the need for the clinician to reach out of the sterile field (such as touching the button interface **32** of the console **20**) to change modes. Thus, in the present embodiment the probe **40** is employed to also control some or all ECG-related functionality of the system **10**. Note that the button interface **32** or other input configurations can also be used to control system functionality. Also, in addition to the visual display **30**, aural information, such as beeps, tones, etc., can also be employed by the system to assist the clinician during catheter placement.

Reference is now made to FIGS. **11**-**12**E in describing various details of one embodiment of the stylet **130** that is removably loaded into the catheter **72** and employed during insertion to position the distal tip **76**A of the catheter in a desired location within the patient vasculature. As shown, the stylet **130** as removed from the catheter defines a proximal end **130**A and a distal end **130**B. A connector **132** is included at the proximal stylet end **130**A, and a tether **134** extends distally from the connector and attaches to a handle **136**. A core wire **138** extends distally from the handle **136**. The stylet **130** is pre-loaded within a lumen of the catheter **72** in one embodiment such that the distal end **130**B is substantially flush, or co-terminal, with the catheter opening at the distal end **76**A thereof (FIG. **10**), and such that a proximal portion of the core wire **138**, the handle **136**, and the tether **134** extend proximally from a selected one of the extension tubes **74**B. Note that, though described herein as a stylet, in other embodiments a guidewire or other catheter guiding apparatus could include the principles of the embodiment described herein.

The core wire **138** defines an elongate shape and is composed of a suitable stylet material including stainless steel or a memory material such as, in one embodiment, a nickel and titanium-containing alloy commonly known by the acronym "nitinol." Though not shown here, manufacture of the core wire **138** from nitinol in one embodiment enables the portion of the core wire corresponding to a distal segment of the stylet to have a pre-shaped bent configuration so as to urge the distal portion of the catheter **72** into a similar bent configuration. In other embodiments, the core wire includes no pre-shaping. Further, the nitinol construction lends torqueability to the core wire **138** to enable a distal segment of the stylet **130** to be manipulated while disposed within the lumen of the catheter **72**, which in turn enables the distal portion of the catheter to be navigated through the vasculature during catheter insertion.

The handle **136** is provided to enable insertion/removal of the stylet from the catheter **72**. In embodiments where the stylet core wire **138** is torqueable, the handle **136** further enables the core wire to be rotated within the lumen of the catheter **72**, to assist in navigating the catheter distal portion through the vasculature of the patient **70**.

The handle **136** attaches to a distal end of the tether **134**. In the present embodiment, the tether **134** is a flexible, shielded cable housing one or more conductive wires electrically connected both to the core wire **138**, which acts as the ECG sensor assembly referred to above, and the tether connector **132**. As such, the tether **134** provides a conductive pathway from the distal portion of the core wire **138** through to the tether connector **132** at proximal end **130**A of the stylet **130**. As will be explained, the tether connector **132** is configured for operable connection to the TLS sensor **50** on the patient's chest for assisting in navigation of the catheter distal tip **76**A to a desired location within the patient vasculature.

As seen in FIGS. **12**B-**12**D, a distal portion of the core wire **138** is gradually tapered, or reduced in diameter, distally from a junction point **142**. A sleeve **140** is slid over the reduced-diameter core wire portion. Though of relatively greater diameter here, the sleeve in another embodiment can be sized to substantially match the diameter of the proximal portion of the stylet core wire. The stylet **130** further includes a magnetic assembly disposed proximate the distal end **130**B thereof for use during TLS mode. The magnetic assembly in the illustrated embodiment includes a plurality of magnetic elements **144** interposed between an outer surface of the reduced-diameter core wire **138** and an inner surface of the sleeve **140** proximate the stylet distal end **130**B. In the present embodiment, the magnetic elements **144** include 20 ferromagnetic magnets of a solid cylindrical shape stacked end-to-end in a manner similar to the stylet **100** of FIG. **2**. In other embodiments, however, the magnetic element(s) may vary from this design in not only shape, but also composition, number, size, magnetic type, and position in the stylet. For example, in one embodiment the plurality of magnets of the magnetic assembly is replaced with an electromagnetic coil that produces a magnetic field for detection by the TLS sensor. These and other variations are therefore contemplated by embodiments of the present invention.

The magnetic elements **144** are employed in the stylet **130** distal portion to enable the position of the stylet distal end **130**B to be observable relative to the TLS sensor **50** placed on the patient's chest. As has been mentioned, the TLS

sensor **50** is configured to detect the magnetic field of the magnetic elements **144** as the stylet advances with the catheter **72** through the patient vasculature. In this way, a clinician placing the catheter **72** is able to generally determine the location of the catheter distal end **76**A within the patient vasculature and detect when catheter malposition is occurring, such as advancement of the catheter along an undesired vein, for instance.

The stylet **130** further includes the afore-mentioned ECG sensor assembly, according to one embodiment. The ECG sensor assembly enables the stylet **130**, disposed in a lumen of the catheter **72** during insertion, to be employed in detecting an intra-atrial ECG signal produced by an SA or other node of the patient's heart, thereby allowing for navigation of the distal tip **76**A of the catheter **72** to a predetermined location within the vasculature proximate the patient's heart. Thus, the ECG sensor assembly serves as an aide in confirming proper placement of the catheter distal tip **76**A.

In the embodiment illustrated in FIGS. **11-12**E, the ECG sensor assembly includes a distal portion of the core wire **138** disposed proximate the stylet distal end **130**B. The core wire **138**, being electrically conductive, enables ECG signals to be detected by the distal end thereof and transmitted proximally along the core wire. A conductive material **146**, such as a conductive epoxy, fills a distal portion of the sleeve **140** adjacent the distal termination of the core wire **138** so as to be in conductive communication with the distal end of the core wire. This in turn increases the conductive surface of the distal end **130**B of the stylet **130** so as to improve its ability to detect ECG signals.

Before catheter placement, the stylet **130** is loaded into a lumen of the catheter **72**. Note that the stylet **130** can come preloaded in the catheter lumen from the manufacturer, or loaded into the catheter by the clinician prior to catheter insertion. The stylet **130** is disposed within the catheter lumen such that the distal end **130**B of the stylet **130** is substantially co-terminal with the distal tip **76**A of the catheter **72**, thus placing the distal tips of both the stylet and the catheter in substantial alignment with one another. The co-terminality of the catheter **72** and stylet **130** enables the magnetic assembly to function with the TLS sensor **50** in TLS mode to track the position of the catheter distal tip **76**A as it advances within the patient vasculature, as has been described. Note, however, that for the tip confirmation functionality of the system **10**, the distal end **130**B of the stylet **130** need not be co-terminal with the catheter distal end **76**A. Rather, all that is required is that a conductive path between the vasculature and the ECG sensor assembly, in this case the core wire **138**, be established such that electrical impulses of the SA node or other node of the patient's heart can be detected. This conductive path in one embodiment can include various components including saline solution, blood, etc.

In one embodiment, once the catheter **72** has been introduced into the patient vasculature via the insertion site **73** (FIG. **10**) the TLS mode of the system **10** can be employed as already described to advance the catheter distal tip **76**A toward its intended destination proximate the SA node. Upon approaching the region of the heart, the system **10** can be switched to ECG mode to enable ECG signals emitted by the SA node to be detected. As the stylet-loaded catheter is advanced toward the patient's heart, the electrically conductive ECG sensor assembly, including the distal end of the core wire **138** and the conductive material **146**, begins to detect the electrical impulses produced by the SA node. As such, the ECG sensor assembly serves as an electrode for detecting the ECG signals. The elongate core wire **138** proximal to the core wire distal end serves as a conductive pathway to convey the electrical impulses produced by the SA node and received by the ECG sensor assembly to the tether **134**.

The tether **134** conveys the ECG signals to the TLS sensor **50** temporarily placed on the patient's chest. The tether **134** is operably connected to the TLS sensor **50** via the tether connector **132** or other suitable direct or indirect connective configuration. As described, the ECG signal can then be process and depicted on the system display **30** (FIG. **9**, **10**). Monitoring of the ECG signal received by the TLS sensor **50** and displayed by the display **30** enables a clinician to observe and analyze changes in the signal as the catheter distal tip **76**A advances toward the SA node. When the received ECG signal matches a desired profile, the clinician can determine that the catheter distal tip **76**A has reached a desired position with respect to the SA node. As mentioned, in one embodiment this desired position lies within the lower one-third (⅓rd) portion of the SVC.

The ECG sensor assembly and magnetic assembly can work in concert in assisting a clinician in placing a catheter within the vasculature. Generally, the magnetic assembly of the stylet **130** assists the clinician in generally navigating the vasculature from initial catheter insertion so as to place the distal end **76**A of the catheter **72** in the general region of the patient's heart. The ECG sensor assembly can then be employed to guide the catheter distal end **76**A to the desired location within the SVC by enabling the clinician to observe changes in the ECG signals produced by the heart as the stylet ECG sensor assembly approaches the SA node. Again, once a suitable ECG signal profile is observed, the clinician can determine that the distal ends of both the stylet **130** and the catheter **72** have arrived at the desired location with respect to the patient's heart. Once it has been positioned as desired, the catheter **72** may be secured in place and the stylet **130** removed from the catheter lumen. It is noted here that the stylet may include one of a variety of configurations in addition to what is explicitly described herein. In one embodiment, the stylet can attach directly to the console instead of an indirect attachment via the TLS sensor. In another embodiment, the structure of the stylet **130** that enables its TLS and ECG-related functionalities can be integrated into the catheter structure itself. For instance, the magnetic assembly and/or ECG sensor assembly can, in one embodiment, be incorporated into the wall of the catheter.

FIGS. **13A-15** describe various details relating to the passage of ECG signal data from the stylet tether **134** to the TLS sensor **50** positioned on the patient's chest, according the present embodiment. In particular, this embodiment is concerned with passage of ECG signal data from a sterile field surrounding the catheter **72** and insertion site **73**, which includes the stylet **130** and tether **134**, and a non-sterile field, such as the patient's chest on which the TLS sensor is positioned. Such passage should not disrupt the sterile field so that the sterility thereof is compromised. A sterile drape that is positioned over the patient **70** during the catheter insertion procedure defines the majority of the sterile field: areas above the drape are sterile, while areas below (excluding the insertion site and immediately surrounding region) are non-sterile. As will be seen, the discussion below includes at least a first communication node associated with the stylet **130**, and a second communication node associated with the TLS sensor **50** that operably connect with one another to enable ECG signal data transfer therebetween.

One embodiment addressing the passage of ECG signal data from the sterile field to the non-sterile field without

compromising the sterility of the former is depicted in FIGS. **13**A-**15**, which depict a "through-drape" implementation also referred to as a "shark fin" implementation. In particular, FIG. **14**A shows the TLS sensor **50** as described above for placement on the chest of the patient during a catheter insertion procedure. The TLS sensor **50** includes on a top surface thereof a connector base **152** defining a channel **152**A in which are disposed three electrical base contacts **154**. A fin connector **156**, also shown in FIGS. **13**A-**13**D, is sized to be slidingly received by the channel **152**A of the connector base **152**, as shown in FIGS. **14**B and **15**. Two ECG lead/electrode pairs **158** extend from the fin connector **156** for placement on the shoulder and torso or other suitable external locations on the patient body. The drape-piercing tether connector **132** is configured to slidingly mate with a portion of the fin connector **156**, as will be described further below, to complete a conductive pathway from the stylet **120**, through the sterile field to the TLS sensor **50**.

FIGS. **13**A-**13**D show further aspects of the fin connector **156**. In particular, the fin connector **156** defines a lower barrel portion **160** that is sized to be received in the channel **152**A of the connector base **152** (FIGS. **14**B, **15**). A hole **162** surrounded by a centering cone **164** is included on a back end of an upper barrel portion **166**. The upper barrel portion **166** is sized to receive the tether connector **132** of the stylet **130** (FIGS. **14**C, **15**) such that a pin contact **170** extending into a channel **172** of the tether connector **132** (FIG. **15**) is guided by the centering hole until it seats within the hole **162** of the fin connector **156**, thus interconnecting the tether connector with the fin connector. An engagement feature, such as the engagement feature **169** shown in FIGS. **13**C and **13**D, can be included on the fin connector **156** to engage with a corresponding feature on the tether connector **132** to assist with maintaining a mating between the two components.

FIG. **13**D shows that the fin connector **156** includes a plurality of electrical contacts **168**. In the present embodiment, three contacts **168** are included: the two forward-most contact each electrically connecting with a terminal end of one of the ECG leads **158**, and the rear contact extending into axial proximity of the hole **162** so as to electrically connect with the pin contact **170** of the tether connector **132** when the latter is mated with the fin connector **156** (FIG. **15**). A bottom portion of each contact **168** of the fin connector **156** is positioned to electrically connect with a corresponding one of the base contacts **154** of the TLS sensor connector base **152**.

FIG. **14**B shows a first connection stage, wherein the fin connector **156** is removably mated with the TLS sensor connector base **152** by the sliding engagement of the lower barrel portion **160** of the fin connector with the connector base channel **152**A. This engagement electrically connects the connector base contacts **154** with the corresponding fin contacts **168**.

FIG. **14**C shows a second connection stage, wherein the tether connector **132** is removably mated with the fin connector **156** by the sliding engagement of the tether connector channel **172** with the upper barrel portion **166** of the fin connector. This engagement electrically connects the tether connector pin contact **170** with the back contact **168** of the fin connector **156**, as best seen in FIG. **15**. In the present embodiment, the horizontal sliding movement of the tether connector **132** with respect to the fin connector **156** is in the same engagement direction as when the fin connector is slidably mated to the sensor connector base channel **152**A (FIG. **14**B). In one embodiment, one or both of the stylet **130**/tether connector **132** and the fin connector **156** are disposable. Also, the tether connector in one embodiment can be mated to the fin connector after the fin connector has been mated to the TLS sensor, while in another embodiment the tether connector can be first mated to the fin connector through the surgical drape before the fin connector is mated to the TLS sensor.

In the connection scheme shown in FIG. **14**C, the stylet **130** is operably connected to the TLS sensor **50** via the tether connector **132**, thus enabling the ECG sensor assembly of the stylet to communicate ECG signals to the TLS sensor. In addition, the ECG lead/electrode pairs **158** are operably connected to the TLS sensor **50**. In one embodiment, therefore, the tether connector **132** is referred to as a first communication node for the stylet **130**, while the fin connector **156** is referred to as a second communication node for the TLS sensor **50**.

Note that various other connective schemes and structures can be employed to establish operable communication between the stylet and the TLS sensor. For instance, the tether connector can use a slicing contact instead of a pin contact to pierce the drape. Or, the fin connector can be integrally formed with the TLS sensor. These and other configurations are therefore embraced within the scope of embodiments of the present disclosure.

As seen in FIG. **15**, a sterile drape **174** used during catheter placement to establish a sterile field is interposed between the interconnection of the tether connector **132** with the fin connector **156**. As just described, the tether connector **132** includes the pin contact **170** that is configured to pierce the drape **174** when the two components are mated. This piercing forms a small hole, or perforation **175**, in the sterile drape **174** that is occupied by the pin contact **170**, thus minimizing the size of the drape perforation by the pin contact. Moreover, the fit between the tether connector **132** and the fin connector **156** is such that the perforation in sterile drape made by piercing of the pin contact **170** is enclosed by the tether connector channel **172**, thus preserving the sterility of the drape and preventing a breach in the drape that could compromise the sterile field established thereby. The tether connector channel **172** is configured so as to fold the sterile drape **174** down prior to piercing by the pin contact **170** such that the pin contact does not pierce the drape until it is disposed proximate the hole **162** of the fin connector **156**. It is noted here that the tether connector **132** and fin connector **156** are configured so as to facilitate alignment therebetween blindly through the opaque sterile drape **174**, i.e., via palpation absent visualization by the clinician of both components.

Note further that the fin contacts **168** of the fin connector **156** as shown in FIG. **15** are configured to mate with the sensor base contacts **154** in such a way as to assist in retaining the fin connector in engagement with the sensor base channel **152**A. This in turn reduces the need for additional apparatus to secure the fin connector **156** to the TLS sensor **50**.

FIG. **16** shows a typical ECG waveform **176**, including a P-wave and a QRS complex. Generally, the amplitude of the P-wave varies as a function of distance of the ECG sensor assembly from the SA node, which produces the waveform **176**. A clinician can use this relationship in determining when the catheter tip is properly positioned proximate the heart. For instance, in one implementation the catheter tip is desirably placed within the lower one-third (⅓rd) of the superior vena cava, as has been discussed. The ECG data detected by the ECG sensor assembly of the stylet **130** is

used to reproduce waveforms such as the waveform **176**, for depiction on the display **30** of the system **10** during ECG mode.

Reference is now made to FIG. **17** in describing display aspects of ECG signal data on the display **30** when the system **10** is in ECG mode, the third modality described further above, according to one embodiment. The screenshot **178** of the display **30** includes elements of the TLS modality, including a representative image **120** of the TLS sensor **50**, and can the icon **114** corresponding to the position of the distal end of the stylet **130** during transit through the patient vasculature. The screenshot **178** further includes a window **180** in which the current ECG waveform captured by the ECG sensor assembly of the stylet **130** and processed by the system **10** is displayed. The window **180** is continually refreshed as new waveforms are detected.

Window **182** includes a successive depiction of the most recent detected ECG waveforms, and includes a refresh bar **182**A, which moves laterally to refresh the waveforms as they are detected. Window **184**A is used to display a baseline ECG waveform, captured before the ECG sensor assembly is brought into proximity with the SA node, for comparison purposes to assist the clinician in determining when the desired catheter tip location has been achieved. Windows **184**B and **184**C can be filed by user-selected detected ECG waveforms when the user pushes a predetermined button on the probe **40** or the console button interface **32**. The waveforms in the windows **184**B and **184**C remain until overwritten by new waveforms as a result of user selection via button pushes or other input. As in previous modes, the depth scale **124**, status/action indicia **126**, and button icons **128** are included on the display **30**. An integrity indicator **186** is also included on the display **30** to give an indication of whether the ECG lead/electrode pairs **158** are operably connected to the TLS sensor **50**.

As seen above, therefore, the display **30** depicts in one embodiment elements of both the TLS and ECG modalities simultaneously on a single screen, thus offering the clinician ample data to assist in placing the catheter distal tip in a desired position. Note further that in one embodiment a printout of the screenshot or selected ECG or TLS data can be saved, printed, or otherwise preserved by the system **10** to enable documentation of proper catheter placement.

Although the embodiments described herein relate to a particular configuration of a catheter, such as a PICC or CVC, such embodiments are merely exemplary. Accordingly, the principles of the present invention can be extended to catheters of many different configurations and designs.

II. Assisted Guidance for Needle/Medical Component

Embodiments of the present invention described herein are generally directed to a guidance system for locating and guiding a needle or other medical component during ultrasound-based or other suitable procedures for accessing with the needle a subcutaneous vessel of a patient, for instance. In one embodiment, the guidance system enables the position, orientation, and advancement of the needle to be superimposed in real-time atop the ultrasound image of the vessel, thus enabling a clinician to accurately guide the needle to the intended target. Furthermore, in one embodiment, the guidance system tracks the needle's position in five degrees of motion: x, y, and z spatial coordinate space, needle pitch, and needle yaw. Such tracking enables the needle to be guided and placed with relatively high accuracy.

Reference is first made to FIGS. **18** and **19**, which depict various components of an ultrasound-based needle guidance system ("system"), generally designated at **1110**, configured in accordance with one embodiment of the present invention. As shown, the system **1110** generally includes an ultrasound ("US") imaging portion including a console **1120**, display **1130**, and probe **1140**, each of which is described in further detail below. Note that the system **1110** bears similarity to the system **10** shown in FIG. **1** with respect to some components, in one embodiment. It should be noted, however, that the ultrasound imaging portion can be configured in one of a variety of ways in addition to what is shown and described herein.

The ultrasound imaging portion of the system **1110** is employed to image a targeted internal portion of a body of a patient prior to percutaneous insertion of a needle or other device to access the target. As described below, in one embodiment insertion of the needle is performed prior to the subsequent insertion of a catheter into a vein or other portion of the vasculature of the patient. It is appreciated, however, that insertion of a needle into the body of a patient can be performed for a variety of medical purposes.

FIG. **19** shows the general relation of the above-described components to a patient **1170** during a procedure to ultimately place a catheter **1172** into the patient vasculature through a skin insertion site **1173**, according to one embodiment. FIG. **19** shows that the catheter **1172** generally includes a proximal portion **1174** that remains exterior to the patient and a distal portion **1176** that resides within the patient vasculature after placement is complete. The system **1110** is employed to ultimately position a distal tip **1176**A of the catheter **1172** in a desired position within the patient vasculature. In one embodiment, the desired position for the catheter distal tip **1176**A is proximate the patient's heart, such as in the lower one-third ($\frac{1}{3}^{rd}$) portion of the Superior Vena Cava ("SVC"). Of course, the system **1110** can be employed to place the catheter distal tip in other locations.

The catheter proximal portion **1174** further includes a hub **1174**A that provides fluid communication between the one or more lumens of the catheter **1172** and one or more extension legs **1174**B extending proximally from the hub. As mentioned, placement of a needle into the patient vasculature at the insertion site **1173** is typically performed prior to insertion of the catheter, though it is appreciated that other placement methods can be employed. Further, it is appreciated that the above discussion is only one example for use of the system **1110**; indeed it can be employed for a variety of uses, such as the placement of needles preparatory to insertion of a catheter as above, the insertion of a needle for other uses, or for the insertion of other medical components into the body of a patient, including x-ray or ultrasound markers, biopsy sheaths, ablation components, bladder scanning components, vena cava filters, etc.

In greater detail, the console **1120** houses a variety of components of the system **1110** and it is appreciated that the console can take one of a variety of forms. A processor **1122**, including non-volatile memory such as EEPROM for instance, is included in the console **1120** for controlling system function and executing various algorithms during operation of the system **1110**, thus acting as a control processor. A digital controller/analog interface **1124** is also included with the console **1120** and is in communication with both the processor **1122** and other system components to govern interfacing between the probe **1140** and other system components.

The system **1110** further includes ports **1152** for connection with additional components such as optional components **1154** including a printer, storage media, keyboard, etc. The ports in one embodiment are USB ports, though other port types or a combination of port types can be used for this and the other interfaces connections described herein. A

power connection **1156** is included with the console **1120** to enable operable connection to an external power supply **1158**. An internal battery **1160** can also be employed, either with or exclusive of an external power supply. Power management circuitry **1159** is included with the digital controller/analog interface **1124** of the console to regulate power use and distribution.

The display **1130** in the present embodiment is integrated into the console **1120** and is used to display information to the clinician during the placement procedure, such as an ultrasound image of the targeted internal body portion attained by the probe **1140**. In another embodiment, the display may be separate from the console. In one embodiment, a console button interface **1132** and control buttons **1184** (FIG. **19**) included on the probe **1140** can be used to immediately call up a desired mode to the display **1130** by the clinician to assist in the placement procedure. In one embodiment, the display **1130** is an LCD device.

FIG. **19** further depicts a needle **1200** used to gain initial access to the patient vasculature via the insertion site **1173**. As will be described in further detail below, the needle **1200** is configured to cooperate with the system **1110** in enabling the system to detect the position, orientation, and advancement of the needle during an ultrasound-based placement procedure.

FIG. **20** depicts features of the probe **1140** according to one embodiment. The probe **1140** is employed in connection with ultrasound-based visualization of a vessel, such as a vein, in preparation for insertion of the needle **1200** and/or catheter **1172** into the vasculature. Such visualization gives real time ultrasound guidance and assists in reducing complications typically associated with such introduction, including inadvertent arterial puncture, hematoma, pneumothorax, etc.

The handheld probe **1140** includes a head **1180** that houses a piezoelectric array for producing ultrasonic pulses and for receiving echoes thereof after reflection by the patient's body when the head is placed against the patient's skin proximate the prospective insertion site **1173** (FIG. **19**). The probe **1140** further includes a plurality of control buttons **1184** (FIG. **19**) for controlling the system, thus eliminating the need for the clinician to reach out of the sterile field, which is established about the patient insertion site prior to establishment of the insertion site, to control the system **1110**.

As such, in one embodiment a clinician employs the ultrasound imaging portion of the system **1110** to determine a suitable insertion site and establish vascular access, such as with the needle **1200**, prior to introduction of the catheter **1172** for ultimate advancement thereof through the vasculature toward an intended destination.

FIG. **18** shows that the probe **1140** further includes a button and memory controller **1142** for governing button and probe operation. The button and memory controller **1142** can include non-volatile memory, such as EEPROM, in one embodiment. The button and memory controller **1142** is in operable communication with a probe interface **1144** of the console **1120**, which includes a piezo input/output component **1144**A for interfacing with the probe piezoelectric array and a button and memory input/output component **1144**B for interfacing with the button and memory controller **1142**.

As seen in FIG. **20**, the probe **1140** includes a sensor array **1190** for detecting the position, orientation, and movement of the needle **1200** during ultrasound imaging procedures, such as those described above. As will be described in further detail below, the sensor array includes a plurality of magnetic sensors **1192** embedded within the housing of the probe. The sensors **1192** are configured to detect a magnetic field associated with the needle **1200** and enable the system **1110** to track the needle. Though configured here as magnetic sensors, it is appreciated that the sensors **1192** can be sensors of other types and configurations, as will be described. Also, though they are shown in FIG. **20** as included with the probe **1140**, the sensors **1192** of the sensor array **1190** can be included in a component separate from the probe, such as a separate handheld device. In the present embodiment, the sensors **1192** are disposed in a planar configuration below a top face **1182** of the probe **1140**, though it is appreciated that the sensors can be arranged in other configurations, such as in an arched or semi-circular arrangement.

In the present embodiment, each of the sensors **1192** includes three orthogonal sensor coils for enabling detection of a magnetic field in three spatial dimensions. Such three dimensional ("3-D") magnetic sensors can be purchased, for example, from Honeywell Sensing and Control of Morristown, N.J. Further, the sensors **1192** of the present embodiment are configured as Hall-effect sensors, though other types of magnetic sensors could be employed. Further, instead of 3-D sensors, a plurality of one dimensional magnetic sensors can be included and arranged as desired to achieve 1-, 2-, or 3-D detection capability.

In the present embodiment, five sensors **1192** are included in the sensor array **1190** so as to enable detection of the needle **1200** in not only the three spatial dimensions (i.e., X, Y, Z coordinate space), but also the pitch and yaw orientation of the needle itself. Note that in one embodiment, orthogonal sensing components of two or more of the sensors **1192** enable the pitch and yaw attitude of the magnetic element **1210**, and thus the needle **1200**, to be determined.

In other embodiments, fewer or more sensors can be employed in the sensor array. More generally, it is appreciated that the number, size, type, and placement of the sensors of the sensor array can vary from what is explicitly shown here.

FIGS. **21**A and **21**B show details of one example of the needle **1200** that can be used in connection with the guidance system **1110** in accessing a targeted internal body portion of the patient, as shown in FIG. **19**, according to one embodiment. In particular, the needle **1200** includes a hollow cannula **1202**, which defines a proximal end **1202**A and a distal end **1202**B. A hub **1204** is attached to the proximal end **1202**A of the cannula **1202** and includes an open end **1204**A that is configured as a connector for connecting with various devices, in the present embodiment. Indeed, the open end **1204**A of the hub **1204** is in communication with the hollow cannula **1202** such that a guide wire, stylet, or other component may be passed through the hub into the cannula.

As shown in FIGS. **21**A and **21**B, a magnetic element **1210** is included with the hub **1204**. As best seen in FIG. **21**B, the magnetic element **1210** in the present embodiment is a permanent magnet, including a ferromagnetic substance for instance, and is ring-shaped so as to define hole **1212** that is aligned with the hollow cannula **1202**. So configured, the magnetic element **1210** produces a magnetic field that is detectable by the sensor array **1190** of the ultrasound probe **1140** so as to enable the location, orientation, and movement of the needle **1200** to be tracked by the system **1110**, as described further below.

In other embodiments, it is appreciated that many other types, numbers, and sizes of magnetic elements can be

employed with the needle **1200** or other medical component to enable tracking thereof by the present guidance system.

Reference is now made to FIGS. **22**A and **22**B, which show the ultrasound probe **1140** of the system **1110** and the needle **1200** in position and ready for insertion thereof through a skin surface **1220** of a patient to access a targeted internal body portion. In particular, the probe **1140** is shown with its head **1180** placed against the patient skin and producing an ultrasound beam **1222** so as to ultrasonically image a portion of a vessel **1226** beneath the patient skin surface **1220**. The ultrasonic image of the vessel **1226** can be depicted on the display **1130** of the system **1110** (FIG. **19**).

As mentioned above, the system **1110** in the present embodiment is configured to detect the position, orientation, and movement of the needle **1200** described above. In particular, the sensor array **1190** of the probe **1140** is configured to detect a magnetic field of the magnetic element **1210** included with the needle **1200**. Each of the sensors **1192** of the sensor array **1190** is configured to spatially detect the magnetic element **1210** in three dimensional space. Thus during operation of the system **1110**, magnetic field strength data of the needle's magnetic element **1210** sensed by each of the sensors **1192** is forwarded to a processor, such as the processor **1122** of the console **1120** (FIG. **18**), which computes in real-time the position and/or orientation of the magnetic element **1210**.

Specifically, and as shown in FIGS. **22**A and **22**B, the position of the magnetic element **1210** in X, Y, and Z coordinate space with respect to the sensor array **1190** can be determined by the system **1110** using the magnetic field strength data sensed by the sensors **1192**. Moreover, FIG. **22**A shows that the pitch of the magnetic element **1210** can also be determined, while FIG. **22**B shows that the yaw of the magnetic element can be determined. Suitable circuitry of the probe **1140**, the console **1120**, or other component of the system can provide the calculations necessary for such position/orientation. In one embodiment, the magnetic element **210** can be tracked using the teachings of one or more of the following U.S. Pat. Nos. 5,775,322; 5,879,297; 6,129,668; 6,216,028; and 6,263,230. The contents of the aforementioned U.S. patents are incorporated herein by reference in their entireties.

The above position and orientation information determined by the system **1110**, together with the length of the cannula **1202** and position of the magnetic element **1210** with respect to the distal needle tip as known by or input into the system, enable the system to accurately determine the location and orientation of the entire length of the needle **1200** with respect to the sensor array **1190**. Optionally, the distance between the magnetic element **1210** and the distal needle tip is known by or input into the system **1110**. This in turn enables the system **1110** to superimpose an image of the needle **1200** on to an image produced by the ultrasound beam **1222** of the probe **1140**. FIGS. **23**A and **23**B show examples of such a superimposition of the needle onto an ultrasound image. Specifically, FIGS. **23**A and **23**B each show a screenshot **1230** that can be depicted on the display **1130** (FIG. **19**), for instance. In FIG. **23**A, an ultrasound image **1232** is shown, including depiction of the patient skin surface **1220**, and the subcutaneous vessel **1226**. The ultrasound image **1232** corresponds to an image acquired by the ultrasound beam **1222** shown in FIGS. **22**A and **22**B, for instance.

The screenshot **1230** further shows a needle image **1234** representing the position and orientation of the actual needle **1200** as determined by the system **1110** as described above. Because the system is able to determine the location and orientation of the needle **1200** with respect to the sensor array **1190**, the system is able to accurately determine the position and orientation of the needle **1200** with respect to the ultrasound image **1232** and superimpose it thereon for depiction as the needle image **1234** on the display **1130**. Coordination of the positioning of the needle image **1234** on the ultrasound image **1232** is performed by suitable algorithms executed by the processor **1122** or other suitable component of the system **1110**.

The sensors **1192** are configured to continuously detect the magnetic field of the magnetic element **1210** of the needle **1200** during operation of the system **1110**. This enables the system **1110** to continuously update the position and orientation of the needle image **1234** for depiction on the display **1130**. Thus, advancement or other movement of the needle **1200** is depicted in real-time by the needle image **1234** on the display **1130**. Note that the system **1110** is capable of continuously updating both the ultrasound image **1232** and the needle image **1234** on the display **1130** as movements of the probe **1140** and the needle **1200** occur during a placement procedure or other activity.

FIG. **23**A further shows that in one embodiment the system **1110** can depict a projected path **1236** based on the current position and orientation of the needle **1200** as depicted by the needle image **1234**. The projected path **1236** assists a clinician in determining whether the current orientation of the needle **1200**, as depicted by the needle image **1234** on the display **1130**, will result in arriving at the desired internal body portion target, such as the vessel **1226** shown here. Again, as the orientation and/or position of the needle image **1234** changes, the projected path **1236** is correspondingly modified by the system **1110**. A target **1238**, indicating the point where the projected path **1236** crosses the plane of the ultrasound image **1232**, can also be depicted on the display **1130** by the system **1110**. As shown in FIG. **23**A, in the present example the target **1238** is located within the vessel **1226** depicted in the ultrasound image **1232**. Note that the position of the target **1238** on the display **1130** can also be modified as the needle **1200** and/or the ultrasound image **1232** are adjusted. The screenshot **1230** also includes an area of probability **1239**, here depicted as a box, which indicates any possible margin of error of the system due to needle length, needle rigidity and flex, field strength of the magnetic element, magnetic interference, possible discrepancy in alignment of the magnetic axis of the magnetic element with the longitudinal axis of the needle, orientation of the sensor array with respect to the ultrasound imaging plane, etc.

FIG. **23**B shows that, in one embodiment, the screenshot **1230** can be configured such that the ultrasound image **1232** and the needle image **1234** are oriented so as to be displayed in a three dimensional aspect. This enables the angle and orientation of the needle **1200**, as depicted by the needle image **1234**, to be ascertained and compared with the intended target imaged by the ultrasound image **1232**. It should be noted that the screenshots **1230** are merely examples of possible depictions produced by the system **1110** for display; indeed, other visual depictions can be used. Note further that the particular area of the body being imaged is merely an example; the system can be used to ultrasonically image a variety of body portions, and should not be limited to what is explicitly depicted in the accompanying figures. Further, the system as depicted and described herein can be included as a component of a larger system, if desired, or can be configured as a stand-alone device. Also, it is appreciated that, in addition to the visual display **1130**, aural information, such as beeps, tones, etc.,

can also be employed by the system **1110** to assist the clinician during positioning and insertion of the needle into the patient.

As mentioned above, in one embodiment it is necessary for the system **1110** to know the total length of the needle **1200** and the location of the magnetic element **1210** thereon in order to enable an accurate depiction of the needle image **1234** and other features of the screenshots **1230** of FIGS. **23**A and **23**B to be made. The system **1110** can be informed these and/or other pertinent parameters in various ways, including scanning by the system of a barcode included on or with the needle, the inclusion of a radiofrequency identification ("RFID") chip with the needle for scanning by the system, color coding of the needle, manual entry of the parameters by the clinician into the system, etc. For instance, an RFID chip **1354** is included on the needle **1200** shown in FIG. **33**A. The probe **1140** or other component of the system **1110** can include an RFID reader to read the information included on the RFID chip **1354**, such as the type or length of the needle **1200**, etc. These and other means for inputting the needle parameters into the system **1110** or detecting the parameters are therefore contemplated.

In one embodiment, a length of the needle (or other aspect of a medical component) can be determined by measurement by the probe/system of a characteristic of the magnetic element, such as its field strength. For instance, in one embodiment the magnetic element of the needle can be positioned at a predetermined distance from the probe or at a predetermined location with respect to the probe. With the magnetic element so positioned, the sensor array of the probe detects and measures the field strength of the magnetic element. The system can compare the measured field strength with a stored list of possible field strengths corresponding to different lengths of needles. The system can match the two strengths and determine the needle length. The needle location and subsequent needle insertion can then proceed as described herein. In another embodiment, instead of holding the magnetic element stationary at a predetermined location, the magnetic element can be moved about the probe such that multiple field strength readings are taken by the probe. Aspects that can be modified so as to impart different field strengths to a set of magnetic element include size, shape, and composition of the magnetic element, etc.

Further details are given here regarding use of the system **1110** in guiding a needle or other medical device in connection with ultrasonic imaging of a targeted internal body portion ("target") of a patient, according to one embodiment. With the magnetic element-equipped needle **1200** positioned a suitable distance (e.g., two or more feet) away from the ultrasound probe **1140** including the sensor array **1190**, the probe is employed to ultrasonically image, for depiction on the display **1130** of the system **1110**, the target within the patient that the needle is intended to intersect via percutaneous insertion. A calibration of the system **1110** is then initiated, in which algorithms are executed by the processor **1122** of the console **1120** to determine a baseline for any ambient magnetic fields in the vicinity of where the procedure will be performed. The system **1110** is also informed of the total length of the needle **1200**, and/or position of the magnetic element with respect to the distal needle tip such as by user input, automatic detection, or in another suitable manner, as has been discussed above.

The needle **1200** is then brought into the range of the sensors **1192** of the sensor array **1190** of the probe **1140**. Each of the sensors **1192** detects the magnetic field strength associated with the magnetic element **1210** of the needle **1200**, which data is forwarded to the processor **1122**. In one embodiment, such data can be stored in memory until needed by the processor. As the sensors **1192** detect the magnetic field, suitable algorithms are performed by the processor **1122** to calculate a magnetic field strength of the magnetic element **1210** of the needle **1200** at predicted points in space in relationship to the probe. The processor **1122** then compares the actual magnetic field strength data detected by the sensors **1192** to the calculated field strength values. Note that this process is further described by the U.S. patents identified above. This process can be iteratively performed until the calculated value for a predicted point matches the measured data. Once this match occurs, the magnetic element **1210** has been positionally located in three dimensional space. Using the magnetic field strength data as detected by the sensors **1192**, the pitch and yaw (i.e., orientation) of the magnetic element **1210** can also be determined. Together with the known length of the needle **1200** and the position of the distal tip of the needle with respect to the magnetic element, this enables an accurate representation of the position and orientation of the needle can be made by the system **1110** and depicted as a virtual model, i.e., the needle image **1234**, on the display **1130**. Note that the predicted and actual detected values must match within a predetermined tolerance or confidence level in one embodiment for the system **1110** to enable needle depiction to occur.

Depiction of the virtual needle image **1234** of the needle **1200** as described above is performed in the present embodiment by overlaying the needle image on the ultrasound image **1232** of the display **1130** (FIGS. **23**A, **23**B). Suitable algorithms of the system **1110** as executed by the processor **1122** or other suitable component further enable the projected path **1236**, the target **1238**, and area of probability **1239** (FIGS. **23**A, **23**B) to be determined and depicted on the display **1130** atop the ultrasound image **1232** of the target. The above prediction, detection, comparison, and depiction process is iteratively performed to continue tracking the movement of the needle **1200** in real-time.

In light of the foregoing and with reference to FIG. **24**, it is appreciated that in one embodiment a method **1240** for guiding a needle or other medical component includes various stages. At stage **1242**, a targeted internal body portion of a patient is imaged by an imaging system, such as an ultrasound imaging device for instance.

At stage **1244**, a detectable characteristic of a medical component such as a needle is sensed by one or more sensors included with the imaging system. In the present embodiment, the detectable characteristic of the needle is a magnetic field of the magnetic element **1210** included with the needle **1200** and the sensors are magnetic sensors included in the sensor array **1190** included with the ultrasound probe **1140**.

At stage **1246**, a position of the medical component with respect to the targeted internal body portion is determined in at least two spatial dimensions via sensing of the detectable characteristic. As described above, such determination is made in the present embodiment by the processor **1122** of the console **1120**.

At stage **1248**, an image representing the position of the medical component is combined with the image of the targeted internal body portion for depiction on a display. Stage **1250** shows that stages **1244**-**1248** can be iteratively repeated to depict advancement or other movement of the medical component with respect to the imaged target, such as percutaneous insertion of the needle **1200** toward the vessel **1226** (FIGS. **23**A, **23**B), for instance.

It is appreciated that the processor **1122** or other suitable component can calculate additional aspects, including the area of probability **1239** and the target **1238** (FIGS. **23**A, **23**B) for depiction on the display **1130**.

It is appreciated that in one embodiment the sensor array need not be incorporated natively into the ultrasound imaging device, but can be included therewith in other ways. FIG. **25** shows one example of this, wherein an attachable sensor module **1260** including the sensors **1192** of the sensor array **1190** is shown attached to the ultrasound probe **1140**. Such a configuration enables needle guidance as described herein to be achieved in connection with a standard ultrasound imaging device, i.e., a device not including a sensor array integrated into the ultrasound probe or a processor and algorithms configured to locate and track a needle as described above. As such, the sensor module **1260** in one embodiment includes a processor and algorithms suitable for locating and tracking the needle or other medical component and for depicting on a display the virtual image of the needle for overlay on to the ultrasound image. In one embodiment, the sensor module **1260** can be included with a module display **1262** for depiction of the needle tracking. These and other configurations of the guidance system are therefore contemplated.

FIG. **26** shows that in one embodiment, a needle holder can be employed to hold and advance the needle **1200** during the ultrasound imaging and needle guidance procedure performed by the system **1110** as has been described. As shown, the needle holder **1270** is pistol-shaped and includes a trigger **1272** for selectively advancing the needle **1200** or other suitable medical component by moving the needle longitudinally away from the barrel of the holder upon pressing of the trigger. So configured, the needle holder **1270** facilitates ease of needle handling with one hand of the clinician while the other hand is grasping and manipulating the ultrasound probe **1140**. In addition, the needle holder **1270** can provide needle movement/rotation assistance such as via a motor, ratcheting, hydraulic/pneumatic drivers, etc. Moreover, a clocking feature can be included on the needle holder **1270** to assist with determining the orientation of the distal tip of the needle **1200** and for facilitating rotation of the needle.

In one embodiment, the needle holder **1270** can be operably connected to the system **1110** such that advancement by the needle holder is automatically stopped when the distal end **1202**B of the needle cannula **1202** reaches the targeted internal body portion or the needle intercepts the ultrasound plane. In yet another embodiment the magnetic element can be included with the needle holder instead of the needle itself. The needle, when temporarily attached to the needle holder, can thus be located and guided by the guidance system without the need for a magnetic element to be attached directly to the needle.

Note that other sensor configurations can also be employed. In one embodiment, an annular sensor can be configured to receive through a hole defined thereby the cannula of the needle. So disposed, a magnetic element of the needle is positioned proximate the annular sensor, which enables ready detection of the magnetic element and location of the needle by the system. The annular sensor can be attached to a surface of the probe, in one embodiment.

FIGS. **27** and **28** depict components of the guidance system **1110** according to another embodiment, wherein an optical-based interaction between the probe **1140** and the needle **1200** is employed to enable tracking and guidance of the needle. In particular, the probe **1140** includes a optical/light source, such as an LED **1280**, and a photodetector **1282** positioned on the probe surface. It is appreciated that the light source and detector can be configured to produce and detect light signals of a variety of ranges including visible, infrared, etc.

The needle hub **1204** includes a reflective surface **1286** capable of reflecting light produced by the LED **1280** and incident thereon. As shown in FIG. **28**, light emitted by the LED **1280** is reflected by the reflective surface **1286** of the needle **1200**, a portion of which is received and sensed by the photodetector **1282**. As in previous embodiments, the processor **1122** of the system console **1120** can be employed to receive the sensed data of the photodetector **1282** and compute the position and or orientation of the needle **1200**. As before, the length of the needle **1200** and/or the position of the reflective surface with respect to the distal end of the needle **1200** are input into or otherwise detectable or known by the system **1110**. Note that the reflective surface can be included at other locations on the needle.

In light of the above, it is appreciated that in the present embodiment the detectable characteristic of the needle **1200** includes the reflectivity of the reflective surface **1286**, in contrast to the magnetic field characteristic of the magnetic element **1210** of previous embodiments, and the sensor includes the photodetector **1282**, in contrast to the magnetic sensors **1192** of previous embodiments. It should be appreciated that in one embodiment, the above-described configuration can be reversed, wherein an optical source is included with the needle or medical component. In this case, light is emitted from the needle and detected by the photodetector **1282** included with the probe **1140** so as to enable location and tracking of the needle. A power source can be included with the needle, such as a watch battery or the like, in order to power the light source of the needle.

More generally, it is appreciated that the needle or medical component can include one or more of these or other detectable characteristics to enable the needle to be tracked and guided toward a target within the body of the patient. Non-limiting examples of other detectable characteristic modalities include electromagnetic or radiofrequency ("RF") (see, e.g., FIGS. **29-30** below), and radioactivity. With respect to RF modalities, it is appreciated that one or more synchronously or asynchronously pulsed frequency sources can be included with the needle as to enable detection thereof by a suitable sensor(s). Or, an RF first source can be coupled with a passive magnet as a second source.

FIGS. **29** and **30** depict components of a guidance system according to one embodiment, wherein EM signal interaction between the probe **1140** and the needle **1200** is employed to enable tracking and guidance of the needle. In particular, in FIG. **29** the needle **1200** includes a stylet **1298** disposed therein. The stylet **1298** includes an EM coil **1290** that is operably connected to the probe **1140** via a tether **1292**. In this way, the EM coil **1290** can be driven by suitable components included in the probe **1140** or system console **1120** such that the EM coil emits an EM signal during operation.

A sensor **1294** suitable for detecting EM signals emitted by the EM coil **1290** of the stylet **1298** is included in the probe **1140**. In the present embodiment, the sensor **1294** is a three-axis sensor for detecting corresponding orthogonal components of the EM signal, though other coil and sensor configurations can also be employed. So configured, the position and orientation of the needle **1200** can be determined, by EM signal triangulation or other suitable process, and displayed by the system in a manner similar to that already described above. As in previous embodiments, the processor **1122** of the system console **1120** (FIG. **18**) can be

employed to receive the sensed data of the EM sensor **1294** and compute the position and/or orientation of the needle **1200**. As before, the length of the needle **1200** and/or the position of the EM coil **1290** with respect to the distal end of the needle **1200** are input into or otherwise detectable or known by the system.

FIG. **30** shows a variation of the EM configuration of FIG. **29**, wherein the respective positions of the EM components is reversed: the EM coil **1290** is included in the probe **1140** and the EM sensor **1294** is included with the stylet **1298** disposed in the needle **1200**. Note that in the embodiments of FIGS. **29** and **30**, the operable connection between the EM coil **1290** and the EM sensor **1294** via the tether **1292** enables the component disposed in the stylet **1298** to be driven by the system **1110**. This also enables correspondence of the particular EM frequency/frequencies emitted by the EM coil **1290** and detected by the EM sensor **1294** to be made. In one embodiment, the configuration shown in FIG. **29** can be varied, wherein no tether operably connects the EM coil and the EM sensor; rather, the EM coil of the stylet operates as a separate component from the probe and its EM sensor and is powered by an independent power source, such as a battery. In this case, the probe/system includes suitable signal processing components configured to detect the EM signal emitted by the EM coil and to process it as necessary in order to locate the needle.

Note that the EM coil and EM sensors can be included at other locations than what is depicted herein. For instance, the EM coil can be included on the needle itself, or on a connector that is attachable to the proximal end of the needle.

FIGS. **31**A-**31**D give further details of the needle **1200** configured according to one embodiment, wherein the needle includes a hub **1304** from which extends the cannula **1202**. A magnetic element **1310** defining a hole **1312** is included in a cavity **1314**A of a housing **1314**. The housing **1314** includes threads so as to threadably engage the needle hub **1304** or other suitable component of the needle or medical component. In this way, the magnetic element **1310** is removably attachable to the needle **1200** via the housing **1314**. Thus, the magnetic element **1310** need not be permanently affixed or included with the needle **1200**, but rather can be removed therefrom when magnetic-based needle guidance is no longer needed. In addition, this enables the magnetic element to be attached to many different types and sizes of needles. Note that in the present embodiment the needle **1200** further includes a distally slidable needle safety component **1320** for safely isolating the distal tip of the needle upon removal of the needle from the patient. Note further that other removable magnetic elements can be employed in addition to what is explicitly shown and described herein.

FIGS. **32**-**33**B give further examples of the needle **1200** including a magnetic element. In FIG. **32**, two bar-like magnetic elements **1340** are disposed so as to orthogonally extend from a hub **1334** of the needle **1200**, illustrating that the magnetic element need not be oriented parallel to the longitudinal axis of the needle. In FIGS. **33**A-**33**B, four magnetic elements **1350** are included in the needle hub **1344**, showing that more than one magnetic element can be included with the needle. Such a configuration may be employed, for example, where limited space prevents one magnetic element from being used. Note the number, shape, and placement of the magnetic elements here is only one example of many possible configurations.

FIGS. **34**A-**34**G give various example configurations of a magnetic element **1360** that defines a hole for receiving the cannula of the needle therethrough. Various shape configurations for the magnetic element **1360** are shown, including a square (FIG. **34**A), a hexagon (FIG. **34**B), a triangle (FIG. **34**C), a rectangle (FIG. **34**D), an oval (FIG. **34**E), an octagon (FIG. **34**F), and a four-sided pyramid (FIG. **34**G). The magnetic elements shown in the accompanying figures are merely examples of the broad number of geometric and other shapes that can be used to define the magnetic element; indeed other shapes not shown explicitly herein are also contemplated.

FIGS. **35** and **36** depict yet another embodiment, wherein a stylet **1390** is included for removable insertion into the hollow cannula **1202** of the needle **1200**. A plurality of permanent magnets **1392**, such as solid, cylindrically shaped ferromagnets stacked end-to-end with each other, is included at a distal end of the stylet **1390**. As shown in FIG. **36**, the stylet **1390** is received within the needle cannula **1202** during insertion of the needle **1200** into the patient. A sensor ring **1396** or other suitable magnetic sensor can be included with or in proximity to the probe **1140** to enable detection of the magnetic field of the magnets **1392**, thus enabling the guidance system to detect the position and orientation of the needle **1200** and superimpose an image thereof atop the ultrasound image produced by the probe **1140** in a manner similar to that described in connection with FIGS. **5**-**7**.

FIGS. **35** and **36** thus illustrate that the magnetic element(s) can be configured in any one of a variety of ways. In one embodiment, for example, the magnetic elements can be disposed more proximally along the stylet length. In another embodiment, the stylet itself can be magnetized or composed of magnetic materials. It is appreciated that the stylet can be configured in one of many different ways, analogous examples of which can be found in U.S. Pat. No. 5,099,845 entitled "Medical Instrument Location Means," and. U.S. Patent Application Publication No. 2007/0049846, filed Aug. 23, 2006, and entitled "Stylet Apparatuses and Methods of Manufacture," both of which are incorporated herein by reference in their entireties. These and other variations are therefore contemplated.

It should be appreciated herein that "stylet" as used herein can include any one of a variety of devices, including guidewires, configured for removable placement within a lumen of the needle to assist in the placement thereof within the patient. In one embodiment, the stylet can include a sharp end that distally extends past a blunt distal end of the needle cannula so as to enable a blunt needle to be inserted into a patient. Note that the stylet in one embodiment stiffens the needle so as to minimize unintended bending thereof during insertion.

FIG. **37** depicts yet another possible embodiment, wherein the needle **1200** includes an annular or donut-shaped magnet **1400** disposed distal to a proximal end **1202**A of the needle cannula **1202**. Note that the magnet **1400** can be positioned in one of several positions along the length of the cannula **1202**, in other embodiments. Positioning of the magnet **1400** relatively closer to the distal needle tip reduces the effects that unintended bending of the needle has on determining and displaying the position of the needle. In yet another embodiment, the needle itself can be magnetized. Note further that the relative places of the sensor and source (e.g., magnet) of the system can be reversed. These and other configurations are also contemplated. Further, note that the discussion herein can be applied to other imaging modalities in addition to ultrasound, including MRI, x-ray and CT scanning, etc.

FIG. **38** depicts a strain gauge **1410** included on a stylet, such as the stylet **1390** shown in FIGS. **35** and **36** for

instance. The strain gauge **1410** can be operably connected to the probe **1140**, console **1120** (FIG. **18**), or other component of the system **1110** via a conductive path **1414**. One example of the conductive path **1414** includes one or more conductive wires disposed in or along the stylet **1390**, for instance. So connected, the strain gauge **1410** acts as a transducer and can provide data relating to bending of the needle in which the stylet **1390** is disposed during needle insertion procedures, given that bending of the needle **1200** will cause similar bending to occur in the stylet **1390**.

These data sensed via bending of the strain gauge **1410** can be forwarded to and interpreted by the processor **1122** (FIG. **18**) or other suitable component of the system **1110** so as to include such bending together with detection of the magnetic element by the probe sensors **1192** (FIG. **20**) in computing the position of the needle **1200**, especially the distal tip thereof. This results in enhanced accuracy for locating and depicting the position of the needle distal tip. Indeed, FIG. **39**A shows flexure of the strain gauge **1410** in one direction as caused by bending of the stylet **1390**, wherein FIG. **39**B shows flexure of the strain gauge in another direction. Such stylet bending is thus detected by the strain gauge **1410** (via changes in electrical resistance within the strain gauge in one embodiment) and forwarded to the system **1110** for use in computing needle position. Note that other suitable sensors and gauges can optionally be used for measuring needle/stylet bending, including a flex sensor **1420**, as shown in FIG. **40** for instance, and capacitance and fiber optic-based strain gauges/sensors. Also, the sensor/gauge may be placed directly on the needle/medical component, in one embodiment.

Embodiments of the invention may be embodied in other specific forms without departing from the spirit of the present disclosure. The described embodiments are to be considered in all respects only as illustrative, not restrictive. The scope of the embodiments is, therefore, indicated by the appended claims rather than by the foregoing description. All changes that come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

1. A guidance system for inserting a needle into a body of a patient in connection with imaging technology, the system comprising:

an imaging device including a probe, the imaging device configured to produce an image of an internal body portion target;

a stylet removably disposed within the needle, the stylet including at least one magnetic element comprising a plurality of passive ferromagnets placed adjacent one another;

at least one sensor included with the probe that senses a magnetic field of the at least one magnetic element of the stylet;

a processor that uses data relating to the magnetic field sensed by the at least one sensor to determine a position of the needle in at least two spatial dimensions relative to the probe; and

a display that depicts the determined position of the needle together with the image of the target.

2. The guidance system as defined in claim **1**, wherein the at least one sensor is disposed on an exterior portion of the probe, and wherein the plurality of ferromagnets are disposed proximate a distal end of the stylet.

3. The guidance system as defined in claim **2**, wherein the at least one sensor includes an annular sensor that is received about a head portion of the probe.

4. The guidance system as defined in claim **1**, wherein the at least one sensor includes orthogonal sensing components so as to enable determination of a position of the at least one magnetic element of the needle in three spatial dimensions and a pitch and a yaw attitude of the at least one magnetic element.

5. The guidance system as defined in claim **1**, further including a strain gauge on the stylet for detecting bending of the needle.

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